United States Court of Appeals

for the Second Circuit

APPENDIX

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NO. 74-2284 et al.

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JOINT APPENDIX TO THE BRIEFS

VOLUME III

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.,

HOOKER CHEMICALS & PLASTICS CORP.,

UNION CARBIDE CORPORATION,

TENNECO CHEMICALS, INC.

and

AIR PRODUCTS AND CHEMICALS, INC.,

Petitioners,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
UNITED STATES DEPARTMENT OF LABOR;
PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR;
and JOHN H. STENDER, ASSISTANT SECRETARY
FOR OCCUPATIONAL SAFETY AND HEALTH,

Respondents.

UNITED STATES COURT OF APPEALS
FILED
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SECOND CIRCUIT

On Petition For Review Of An Order Of
The Occupational Safety and Health Administration,
United States Department of Labor

Submitted by:
MARTIN I. SHELTON
Shea Gould Climenko & Kramer
330 Madison Avenue
New York, New York 10017

Attorney for The Society of
the Plastics Industry, Inc.

Prepared by:
ALLAN J. TOPOL
JONATHAN M. WEISGALL
Covington & Burling
888 Sixteenth Street, N.W.
Washington, D.C. 20006

Attorneys for Hooker Chemicals
& Plastics Corp., Tenneco
Chemicals, Inc., and Air
Products and Chemicals, Inc.

November 12, 1974

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TENNECO CHEMICALS, INC. TESTIMONY

OSHA HEARING

JUNE 25, 1974

My name is Joseph Fath; I am a Vice President of Tenneco Chemicals, Inc. and the General Manager of its Organics and Polymers Division. I was graduated from Cornell University with a Bachelor's Degree in chemistry in 1944. For the past 28 years, I have held various research, business development and senior management positions in the chemical sector, including direct research, development and technical experience of 14 years in the polyvinyl chloride field and an overall experience of 18 years in that industry.

Tenneco opposes OSHA's proposed permanent standard for vinyl chloride and generally supports the position outlined by the witnesses for the Society of Plastics Industry. The standard of no detectable amount of ambient vinyl chloride is not feasible. Adoption of the proposed OSHA standard would leave Tenneco with the following options:

(1) We would have to place all operating and support personnel at our PVC manufacturing sites in respirators all of the time; or

(2) Tenneco would have to cease manufacture of PVC which we are currently producing at a rate of 240 million pounds per year with 500 million pounds projected for 1975 and beyond.

The consequences of the latter option have already been reviewed by the SPI. I want to reiterate on behalf of Tenneco that discontinuing the manufacture of PVC would have tremendously disruptive effects on the defense, wire and cable, construction, automotive, and the phonograph record industries.

It is neither safe nor feasible to place vinyl chloride workers in respirators for the full duration of a work shift. However, given the serious nature of available scientific and medical evidence regarding potential human health effects of vinyl chloride inhalation, management, union leadership, the Federal government, and the medical community must, in concert, agree that the only conceivable course of action for industry is the maximum feasible reduction of human exposure

to airborne concentrations of vinyl chloride monomer. Though a no detectable standard is not feasible, it is, nevertheless, incumbent upon the industry to take every technologically and economically feasible step to reduce levels of ambient vinyl chloride.

I am accompanied by Dr. Paul Lobo, Director of our Technical Group for Tenneco's Organics and Polymers Division, and by Mr. Philip Scarito, Works Manager of our Burlington, New Jersey facility. They will supplement my general presentation with a more detailed analysis of the proposed standard's lack of feasibility from the engineering and plant operations viewpoint, while pointing out the steps that Tenneco has taken or will take to reduce worker exposure to vinyl chloride. I shall outline to you the elements of a position which Tenneco considers to be feasible and which incorporates the best work practices within the shortest possible period of time. It is appropriate at this point, however, to profile briefly Tenneco's facilities and work force.

Tenneco is involved in all three stages of production associated with the various polyvinyl chloride manufacturing operations. Our Pasadena, Texas facility produces vinyl chloride monomer. Our Flemington and Burlington, New Jersey plants manufacture 36 different resins through a number of complex polymerization processes. The various resins manufactured required different operating procedures and involve different types of technology. The potential vinyl chloride exposure problems, therefore, also differ widely from one process to another within the same site.

Further, at Burlington we process resins with other chemicals and additives to form semi-finished vinyl compounds for subsequent fabrication. Our facilities at Nixon and Carlstadt, New Jersey and at Newton, Massachusetts process vinyl chloride resins into a variety of fabricated products both rigid and flexible. At Tenneco, 15 employees are currently involved in monomer production, 343 in the manufacture of polyvinyl chloride resins, and 456 in the manufacture

of fabricated products. Tenneco's production capacity for polyvinyl chloride is about to be significantly augmented by the opening of a new facility at our Pasadena, Texas chemical complex, using a new large reactor technology. This facility will employ an additional 60 individuals.

Tenneco has researched the work history and cause of death of the 20 persons, out of a total of 1,029 personnel employed over the course of our 17 years of operation, who have died while still employed at our monomer and polymer facilities. None have died from angiosarcoma of the liver. Tenneco participated in the epidemiological survey of the industry conducted by Tabershaw-Cooper Associates whereby cause of death was researched for certain former Tenneco employees. Again, no former Tenneco employee, found by the Tabershaw-Cooper researchers, had died from cancer of the liver.

The vinyl chloride industry has grown during the last 30 years from production at the multi-hundred million pound level to today's five billion pounds. During this same period, employee exposure to vinyl chloride has been drastically reduced because technical advances have enabled automation of some manual operations, ventilation has improved, leaks have been subjected to greater controls, and work practices have improved materially. In this regard, it is interesting to note that the 13 U.S. PVC industry employees discovered to date to have contracted angiosarcoma of the liver were employed at four of the five oldest plants in the industry. There is up to now no human experience data indicating that angiosarcoma will result from the substantially lower levels of exposure that have existed in the industry during more recent years.

We cannot, however, ignore these tragic worker deaths. We must, therefore, take every reasonable and feasible step, first, to reduce individual employee exposure and, second, to reduce the number

of employees potentially exposed within the estimated 700,000 employee work force of the vinyl industry. This must be accomplished without causing severe consequences to numerous consumer and defense activities that would result from a serious disruption in the production of polyvinyl chloride, the nation's most versatile thermoplastic polymer.

The proposed permanent standard assumes that members of the industry will be able to meet its requirements through a combination of engineering improvements, work practice changes, and the use of respirators. The assumption is not justified. Compliance with the proposed standard cannot be accomplished as a practical matter. Because of the current configuration of industry plants, the fact that batch processing is employed and the current state of technology, the practical effect of the proposed standard will be to require employees to wear respirators essentially all of their time spent in the regulated work areas described in the standard. The result is not viable

for plant operations and is inconsistent with the proposed standard. Dr. Lobo will describe in greater detail the obstacles to eliminating vinyl chloride exposure through engineering changes, and Mr. Scarito will describe the likely consequences for employee safety, morale and production efficiency, of the necessity of employees' wearing respirators during the entire day. I shall now address myself to some of the specifics of what we at Tenneco feel we can accomplish in reducing worker exposure to vinyl chloride in our polymerization and processing facilities.

While, as I have already noted, we support the industry proposal outlined by the Society of Plastics Industry for the three types of operations, namely VCM production, PVC resin production and fabrication facilities for vinyl goods, I would like specifically to state Tenneco's position on its most significant manufacturing activities -- that of PVC resin production and fabrication facilities for vinyl goods.

The elements of this position are as follows:

(1) We propose a constant, sequential monitoring of all areas within the PVC polymerization plant sites. We consider this method a vastly superior and a more conscientious technique of checking existing levels than personnel monitoring systems. We believe that the proposed system will do more to prevent and correct prolonged dosages of vinyl chloride than any other mechanical correction possible in our existing plants. Further, it will enable us to diagnose with greater reliability the existence of potential problem areas. The proposed system will be connected to gas chromatography apparatus and will yield a permanent record of constant exposures throughout the plant site. We have these systems on order and expect them to be delivered within a reasonable time.

(2) It is essential and self-evident that the permanent standard recognizes the need for a time period during which engineering and operational changes can be made in line with the more detailed

proposals you will hear from Messrs. Lobo and Scarito. I understand that the standard must by law go into effect on October 5, 1974. Exposure levels to be complied with as of that date will apply to PVC plants before engineering solutions, design specifications and purchase and delivery of vital equipment can be accomplished, because completion of these actions will take two to three years. It must be noted that since the entire industry will be required to make comparable changes, there will be delays beyond normal lead time. Thus, our proposal will include exposure levels which are based upon what we consider to be the practical elements of compliance feasibility.

(3) Another vital element of our position is that we propose the drastic reduction of residual monomer content in the polyvinyl chloride resin to be delivered to our customers to 100 ppm or 0.01% maximum by October 5, 1977. This residual monomer constitutes the only source of VCM which is released from PVC resin because PVC does not depolymerize. In other words, the polymer itself, once formed,

does not generate vinyl chloride monomer. By reducing this level and processing the PVC resin with such reduced levels in the fabricating plants, we have determined from preliminary experimental results, that we would expect to remove essentially the entire work force involved in the vinyl fabrication industry from any vinyl chloride exposure. When it is recognized that only about one percent of the 700,000 workers in the vinyl industry are actually employed in the manufacture of vinyl chloride monomer and polyvinyl chloride, the remainder being employed in the processing sector, this plan will eliminate within a short time, any possible health hazard for 99% of the vinyl industry work force. To us, this represents the most rapid containment of the current problem with the proposed exposure levels for the remaining industry segments representing the limits of technological feasibility.

(4) Let me now state our position with regard to employee exposure levels in our PVC polymerization plants. It will be feasible

for Tenneco to comply with the levels of exposure presented by the SPI witnesses. Those levels call for, as of October 5, 1974, a ceiling of 40 ppm before donning of respiratory equipment is required, with a 25 ppm TWA. As of October 5, 1975, the ceiling should be lowered to 25 ppm maximum, before respiratory equipment is required. As of October 5, 1976, we propose adding to the ceiling of 25 ppm maximum, a TWA of 10 ppm based on an eight-hour day. Once we have had some experience with constant sequential monitoring, we will have a more realistic basis for knowing whether we can accelerate the attainment of the levels in the proposed standard presented by the SPI witnesses. Every effort will be made to reach these levels within the shortest practicable time.

To reach these levels of exposure in the time frame I have described, Tenneco will probably have to spend in excess of $10,000,000 and incur additional annual operating costs amounting to millions of dollars. Until medical data and experiment can establish a safe or

widely acceptable risk threshold for vinyl chloride exposure, we feel that we must do everything feasible to reduce worker exposure.

In sum, although the standard proposed by OSHA is not feasible, Tenneco intends to do everything reasonable and feasible not only to reduce exposure of workers in monomer and polymer facilities, but also to assure protection of the much larger work force that processes PVC resins.

We hope that reason will prevail and that all interested parties including the Federal Government, labor, the medical community and the management of the polyvinyl chloride industry can communicate and cooperate toward the important goal of minimizing vinyl chloride exposure to the maximum extent feasible, without causing the severe economic consequences that could attend application of unrealistic and impossible standards.

My name is Paul Lobo and I am Director of the Technical Group for the Organics and Polymers Division of Tenneco Chemicals. In this capacity, I am in charge of Engineering as well as the Research and Development activities of this division. I received both B.S. and M.S. degrees in chemical engineering from the Massachusetts Institute of Technology and a doctorate in chemical engineering from the University of Michigan. I have had 19 years experience in the chemical industry in the field of research and development, engineering and technical management. Eight of these years were spent developing commercial processes from the laboratory through the pilot plant to commercial plant design and start-up.

Based on the presently available technology, it is not feasible for existing polyvinyl chloride facilities to meet the proposed OSHA standard through engineering changes. Further, the proposed standard cannot be met through any combination of engineering changes and altered work practice methods, without the use of respirators 100 percent of the time. As I understand it, the proposed standard does not contemplate

use of respirators 100 percent of the time. If the standard were to result in the full time use of respirators, as Mr. Fath has pointed out and as Mr. Scarito will detail, we are convinced that this would not be a practical mode of operation. I will defer to Mr. Scarito on the respirator and work practices questions and focus my remarks on the engineering implications of the standard.

Tenneco's polymer facilities range in age between 5 and 17 years. Our Flemington, New Jersey plant was originally constructed in 1957, and extensively rebuilt in 1969. It produces approximately 85 million pounds per year. Our Burlington, New Jersey facility consists of four distinct plants having a total capacity of 150 million pounds per year. Two of these make PVC resins, homopolymers and vinyl acetate copolymers, by the suspension process, and were built in 1961 and 1964 respectively. Plants making resin by the dispersion method were added in 1965 and 1969. A new, large, suspension resin plant is scheduled to begin operations at our Pasadena, Texas facility in the fall of 1974. It will produce approximately 250 million pounds per year.

All our plants currently in operation were constructed based upon the best knowledge of vinyl chloride processing available at the point in time when they were built. None were built with the knowledge that exposure of vinyl chloride monomer may constitute a serious health risk to workers beyond the known anesthetic and flammable properties of this gas. Although up-to-date engineering practices were used in their design and construction, there exists no practical, quick corrective means to bring these facilities into conformance with a standard of no detectable level of VCM in the plant areas. In this conclusion, I include even our most modern facility that is expected to begin operation in Texas this coming fall.

In the design of PVC polymerization facilities, a batch or discontinuous chemical process is employed by Tenneco and the rest of the industry. Such a process requires opening of processing vessels after one or more batches have been polymerized; the removal of water, unreacted monomer and inerts from the polymer after the reaction through a series of stripping, venting, and drying steps, and finally the bagging or bulk loading of a solid material at the end of the process. All of the Tenneco plants as

well as most others in the industry have, for safety reasons, been designed so that these various operations are separated from one another by considerable distances. Therefore, the problem of emissions is not confined to a relatively small and manageable area, but is one that exists throughout an entire multi-acre plant site.

On the other hand, vinyl chloride monomer production at our Pasadena, Texas plant and all other industry facilities is a continuous chemical process carried out within a substantially closed system. It is easier to reduce monomer emissions and hence ambient levels when one is dealing with a continuous, closed system. It is for this reason that we support the proposal presented by the SPI witnesses for a more stringent standard for monomer plants than for polymer plants.

There are four principal facets of the polymer manufacturing process that can lead to worker exposure to vinyl chloride monomer. First, the monomer usually arrives at the polymer facility by tank car or by truck and at this unloading stage, some exposure is unavoidable since transfer hoses must be hooked and unhooked. Workers currently

wear air supplied respirators for these unloading tasks. However, because of the coupling and uncoupling steps involved, emissions in this area can contribute to the general levels of VCM on the site. We have changed our unloading techniques to reduce these emissions considerably, even though these changes represent a lowering of operating efficiency. We are not able, however, to eliminate entirely the escape of some VCM in this area.

Second, in all of our existing plants the walls of reactor vessels must be cleaned by workers since deposits of polyvinyl chloride form on them during the polymerization process. These deposits prevent the heat, which is released during the reaction, to be removed through the wall of the vessel, thus interfering with the process and creating a potential safety hazard. Further, if these deposits are permitted to remain, such safety devices as relief valves, may become clogged posing a further threat to workers' safety. Additionally, if a clean reactor is not used, product quality can be degraded to a point where it becomes useless to the plastic processor.

We have found means to increase the number of batches that can be processed before it is required that a worker enter the reactor to clean it. Frequency of reactor entry can be further reduced through employment of certain cleaning technology which Tenneco is currently developing, and our future plans to minimize worker exposure presuppose installation of improved cleaning processes or procedures. However, even with these processes, it is very likely that periodic vessel entry will be required to assure that the

mechanical internals are in working condition and emergency relief valves have not become blocked by polymer and thus rendered inoperable.

A third source of worker exposure is leakage from mechanical equipment, i.e., compressors, pumps and valves. In the design of our facilities, sound engineering practices were used to select such equipment; however, this was in accordance with known technology, exposure limits then considered safe and the nature of the processes utilized. Contrary to the claims that some have made, this leakage cannot be eliminated through installation of a few readily available substitute valves and pumps.

There do exist some low volume pumps that have been field proven which can help "tighten up" certain stages of our operations. These pumps will be installed as part of our program to minimize worker exposure. For higher volume applications, there are available so-called canned pumps which might reduce vinyl chloride leakage but

they have not been tested in PVC plant applications such as slurry service. We cannot be confident of their feasibility in our installations at this time.

The fourth and most significant amount of vinyl chloride escape results from the drying stage of the resin production process. The drying stage is a necessary facet of suspension and dispersion processes used in the Tenneco plants. Some of our dryers are gigantic rotating kilns, 50 feet long and 10 feet in diameter, which use immense volumes of air, 30,000 cubic feet per minute or more, to remove water from the resins. During this processing step, quantities of residual monomer not removed in the earlier stripping stage are removed from the polymer and some of the monomer escapes into the plant site area.

One approach which has been suggested to remove VCM from the ambient air is adsorption by activated carbon. This is considered

wholly impractical where large volumes of air and small concentrations of VCM are involved. In our new Pasadena plant, we have included carbon adsorption to recover VCM from two small process streams, neither of which contains air, but even this limited application has yet to be tested on a commercial plant scale.

Because of the factors I have just described, it is not feasible by engineering changes utilizing presently available technology, to modify our existing plants to meet the proposed standard, nor can a combination of work practices and engineering changes achieve that result. However, steps can be taken to reduce employee exposure to vinyl chloride. With these steps, Tenneco hopes to reduce vinyl chloride monomer exposure levels to 10 parts per million (time-weighted-average) with a ceiling excursion of 25 parts per million by October 1976.

Our program includes installation of:

A very extensive sequential area monitoring system to insure conformance and to indicate excursions;

New, low leakage pumps;

Equipment to minimize reactor entry for cleaning;

Ventilation equipment totally beyond the scope of our current operation; and,

An elaborate manifolding system so as to permit utilization of respiratory equipment where needed.

It will also include the isolation of certain key areas from worker exposure and extensive addition of processing equipment to attain stripping and monomer recovery efficiencies far beyond our present capability.

It should be noted that these extensive modifications dictate the prompt placement of orders for such equipment since current delivery

and installation schedules range upwards of two years. While we have already ordered some of this equipment, it must also be realized that design specifications cannot be made until a permanent standard has, in fact, been defined. Such design specifications do not exist for the proposed "no-detectable" level.

In addition, Tenneco has underway significant research and development efforts already mentioned by Mr. Fath, the goal of which is to eliminate the highest possible percentage of monomer from the resin prior to the drying stage. To date, our laboratory studies have shown that monomer levels in certain of our resins can be reduced substantially below the 0.01% level, which is 100 ppm. Our research and development program is currently geared toward translating these results into the commercial plant. These improved techniques will require the further addition of equipment which is subject to the same lengthy delivery schedules.

This developmental effort, if successful, should result not only in a drastic lowering of the residual monomer content in our resins, but also should aid in greatly reducing the amount of monomer released in the drying stage. This will aid in reducing monomer levels in the PVC plant site area. In addition and most important, the downstream vinyl processors will benefit from these lower contained monomer levels in the resin, resulting in the substantial elimination of exposure to the hundreds of thousands of workers involved in that industry.

Preliminary studies show that the capital expenditures needed to meet our goal of 10 parts per million time-weighted-average monomer exposure in 1976 will probably exceed $10 million and that additional labor and operational costs will total in the millions of dollars per year. Even after these extensive and costly changes, we estimate that certain job classifications will be required to wear respirators some

part of the time. We believe that this percentage of respirator use represents the tolerable maximum for Tenneco's workers.

Tenneco will continue to seek engineering solutions to the problem of worker exposure to vinyl chloride monomer. My testimony has concerned itself with the problems we face and the plans we currently have to deal with them based on research and development goals and current technology.

My name is Philip Scarito, and I am the Works Manager of Tenneco's Burlington, New Jersey polymer and compounding facility. I was graduated from the Massachusetts Institute of Technology in 1937 with a Bachelor's Degree in chemistry. For the past 18 years, I have served in Plant Manager assignments at three separate Tenneco polyvinyl chloride facilities. For the past eight (8) years, my responsibilities at the Burlington site have encompassed all aspects of the manufacturing operations including work practices and safety.

As both Mr. Fath and Dr. Lobo have already pointed out, compliance with the proposed permanent work standard would require for the foreseeable future, use of air supplied respirators by polyvinyl chloride workers 100 percent of the time that they spend in regulated work areas which would encompass all of the physical plant. Based upon my long experience in polyvinyl chloride facilities, I feel strongly this is neither an appropriate, safe or feasible solution to the problem of worker exposure to vinyl chloride monomer since it would entail substantial health and safety risks in and of itself. In this regard,

Tenneco has already experienced one lost time accident when a worker suffered a fall from a ladder as a result of his using a lengthy air hose attached to a breathing apparatus.

A typical vinyl chloride polymerization facility is a multi-story operation, has many catwalks or narrow passageways, stairwells, moving machinery and, in general, areas where dragging an extended length of hose become difficult and hazardous. I believe the safety hazards inherent in a man's being required to trail behind him a 25 ft. or longer length of air hose are quite obvious and do not require further elaboration. This hazard is increased significantly in several jobs where the travel distance of an operator for certain specific operations could require lengths of air hose well in excess of 100 ft. Added to the built-in hazards of long lengths of hose is the fact that certain operations involve multi-level work assignments. Backpack type air supply is neither a practical nor an acceptable substitute for hose supplied air because of the weight and bulk of the units. Also, I could not from my experience recommend regular use of so-called cannister masks under a no-detectable level standard because first, of the difficulty of ensuring their continued

effectiveness with continuing exposure; and second, because their failure cannot be detected by the worker.

The full face masks required by the proposed permanent standard limit a worker's field of vision on both a vertical and a horizontal plane. They reduce very significantly and, in the case of some respirators, totally interfere with a worker's hearing. Many of the manufacturing procedures in a polyvinyl chloride facility require that an employee be able to hear and to respond to audible alarms. This is vital both from a process control point of view as well as a pure and simple safety consideration. Air supplied respirators definitely reduce a worker's ability to hear some of these important alarms at the very least; and in many cases, will definitely prevent him from hearing and responding to others. Likewise, the wearing of such a respirator will make difficult communicating by voice, and this creates an additional operational inefficiency as well as possibly generating a very real potential hazard.

It is my feeling that the use of respirators for prolonged periods will definitely contribute to worker fatigue, which will again

increase the possibility of unnecessary injuries. I am sure that the tolerance of continuous wearing of respirators will vary considerably from worker to worker; but in a polyvinyl chloride operation, we cannot afford to introduce factors which diminish a man's reaction capabilities. There will undoubtedly be some employees who are susceptible to claustrophobia, and it is my opinion that these employees will simply not be able to wear the required respirators. Additionally, I suspect that longtime use of air respirators may well lead to lung and throat damage.

A further problem, which is very real, is that I feel it will become difficult, if not impossible, to staff our plants when prospective employees know that they will be required to wear respirators full time. Realistically, I feel that we may lose many of our key present employees for the same reason.

Though nose and mouth respirators as compared to full face respirators reduce some of the problems of the limited field of vision, hearing, and claustrophobia, they still present the problems of accidents from tripping, constriction of vertical vision, and the possible injury to throat and lung tissues from extended use.

The drafters of the proposed standard appear to have recognized the problems I have outlined. The standard states: "Respirators shall be used only in cases of emergency...and...respirators may not be used in lieu of feasible engineering controls or work practice methods." Since, as has already been discussed, engineering controls and work practice methods cannot yield a no-detectable level environment, the consequence of the standard is to require use 100 percent of the time of air supplied respirators, an outcome that OSHA and industry apparently agree is not acceptable.

Tenneco has undertaken the following steps to reduce ambient vinyl chloride in plant areas through use of work practices and tolerable maximum use of respirators:

(1) Taking siding from building;

(2) Added ventilation;

(3) Installation of manifold air supplied system to completely cover all of the reactor building areas at all levels as well as other necessary plant areas;

(4) Issuance to each worker of a full face air supplied respirator for reasonable use when necessary;

(5) Improved stripping of residual monomer from the wet slurry and thereby reducing vinyl chloride in the air during subsequent processing;

(6) As an interim step, prior to the installation of sequential monitoring, we have introduced the use of organic vapor analyzer monitoring to identify minute leaks not otherwise detectable; and

(7) Improved work practices relating to the cleaning of reactors.

(4) Issuance to each worker of a full-face air-supplied respirator for reasonable use when necessary;

(5) Improved stripping of residual monomer from the wet slurry and thereby reducing vinyl chloride in the air during subsequent processing;

(6) As an interim step, prior to the installation of sequential monitoring, we have introduced the use of organic vapor analyzer monitoring to identify minute leaks not otherwise detectable; and

(7) Improved work practices relating to the cleaning of reactors.

Thank you.

JUDGE KUNT: All right. Mr. Klein?

MR. KLEIN: When I ask you a question, if any of you people feel competent to reply to it, you just do it, please.

Do you have with you today your measurements in monitoring that have been taken at your various plants?

MR. PATH: No, we do not have them with us, Mr. Klein, but they are available.

MR. KLEIN: Can you tell us, at each of your plants, representative figures with respect to worker exposure, if you remember them?

MR. PATH: Based on the personnel monitoring data that we now have, our figures fall into various categories,

if I may speak of orders of magnitude. The Flemington site--we currently have two polymerization sites in our operation at Flemington and Burlington, New Jersey--the Flemington site, the majority of our readings are in the--all the way down to non-detectable in some areas to perhaps the 10 to 12 ppm area, with a minority of the readings in the perhaps 15 to 50 ppm area, and with a very low percentage above that in areas now identified as those requiring respiratory equipment.

MR. SMITH: Would it be correct to assume that the areas you indicated as the source points, the problem source points, are the areas that would go from 15 to 50 ppm?

MR. FATH: No, I think rather those that would be above the 50 ppm level. These have been reasonably identified as those requiring respiratory equipment now in normal operation.

MR. SMITH: Have you been able to identify the source points with respect to the 15 to 50 ppm area?

MR. FATH: These are random readings in the various operator areas, and we have identified some of those problem areas. But remembering that those readings are always after-the-fact readings, we do not know the extent of the duration of these, let's call them excursions above a normal pattern.

MR. SMITH: Could you identify for us now what the exposure points are that you have identified at the 15 to 50

MR. FATH: For the most part they are in the reactor area, as I recall the data.

MR. KLEIN: Would you be able to make that information available to us, sir?

MR. FATH: Yes, I would.

MR. klein: Now that we have covered the Flemington plant, could we go through the rest of the plants, please?

MR. FATH: Yes. At our Burlington plant--and I might ask Mr. Scarito to comment in greater detail--taking the same patterns of orders of magnitude into consideration, our Burlington plant is an entirely different plant in that it is what we consider a mixed plant, wherein we practice some four different polymerization technologies within the same site, in buildings that are in rather close proximity to one another.

And so we have a much larger incidence of exposures in the readings of, let's say, 15 to 50 part per million area than we would at Flemington.

And these are scattered over a much wider job classification and area categories.

MR. klein: Could we go on to the rest of your plants briefly?

MR. FATH: Well, those are our two existing polymerization plants now; as I indicated in my testimony, we are constructing a PVC plant in Texas, but that is not yet

in operation. We do have there a monomer producing facility, a small one, and in that plant our levels are considerably lower, mostly in the area between 0 and 10 parts per million, due to the fact that it is a continuous process and it is totally outdoors.

MR. KLEIN: Have you been able to project at the plant under construction approximate exposure levels to employees there?

MR. FATH: We feel that that plant will be able to meet the ultimate level that we have proposed as a limit of feasibility sooner than the remainder of our plants, for which we have projected a two-year level to achieve that point.

MR. KLEIN: What technical controls or work practices will exist at the new plant that would account for the difference in terms of your lowering the exposure levels?

MR. FATH: The fundamental difference in that plant, aside from the fact that it will be a brand-new plant, with new equipment not subject to prior wear, is the fact that it will have fewer but larger reactors and that, due to its southern location, will have a larger percentage of its total equipment located out of doors.

As to the work practices, perhaps Dr. Lobo can add to it.

DR. LOBO: There will be two other elements which

we feel will assist us in reducing the exposure to the levels of VCM in the plant site area. One of these will be that we will receive the monomer by pipeline. The second is that this technology which we have licensed does provide for less problems in the reactor cleaning area.

MR. KLEIN: How have you dealt with the problems in the cleaning area at the new plant?

DR. LOBO: This is licensed technology, Mr. Kline, and I am not free to discuss the details of it, but it does make it simpler to clean the reactor between batches and it minimizes the problems in the cleaning process.

MR. KLEIN: Can you tell us whether it is an automated process?

DR. LOBO: The present state of technology requires that the reactor be open between each batch, and at this stage it is necessary for a man to enter the reactor between each batch. That is the present state of the technology.

But the problems are less than in the conventional polymerization system or the other technology practiced in the country.

MR. KLEIN: The statement you just made applies to the new plant?

DR. LOBO: To the new plant, correct.

MR. KLEIN: I would like to direct your attention to page 5 of your testimony, the only full paragraph. Have

you followed employees who had retired and were no longer employed by Tenneco?

MR. FATH: We have to the extent possible. I don't believe we would have a complete record of that, since there has been a great bit of movement.

MR. KLEIN: On page 6 you talk about automation of some manual operations. Could you tell us which operations you have automated, the details about those operations?

DR. LOBO: Well, as I mentioned in my testimony, we have reduced the exposure of employees by reducing the number of times that we have to clean the reactors--and this has been done by the installation of a high-pressure cleaning system in two of our plants, high-pressure water system.

This is probably the greatest area where we have made progress, from the standpoint of automation.

MR. KLEIN: How often do employees now have to go into the reactor with the use of this method?

DR. LOBO: We practice a number of different technologies: in our dispersion plant, there is one problem; in the suspension, homopolymer, another problem; and copolymer and so forth. So it varies, but somewhere between once every five batches to perhaps once every twenty or twenty-five, depending upon the process.

MR. KLEIN: And could you give us a range as to how long it takes to clean a reactor?

DR. LOBO: About 30 minutes.

MR. KLEIN: Are there any other means of automation that you have instituted to reduce employee exposure?

DR. LOBO: We have, or will have, in our new facility a highly automated system, which will minimize the number of employees required to operate the plant, and minimize the number of employees that will be necessary in the polymerization reactor area, which in all our plants is the area of the highest level of VCM in the air.

MR. KLEIN: Is that information licensed as well?

DR. LOBO: Yes, it is.

MR. PATE: Mr. Klein, I might add another aspect of the automation which was alluded to previously. For a number of years we have had detection devices throughout our entire plant, which addressed themselves to gross excursions and lower explosive limits, which set off ventilation and deluge system. I believe these have existed throughout most plants in the industry.

But they, of course, addressing themselves to gross excursions of monomer, are devices that have existed for a time much less long than the time the industry has been in operation.

What I am saying is, that it is unlikely that those devices had been installed in plants operating in the 1940's and many years ago.

MR. KLEIN: Now, directing your attention to the improved ventilation systems, are there ventilation systems in the new plant that do not exist in your older plants?

DR. LOBO: No, there is nothing different in that aspect. What we have done in recent years is to increase the number of air changes per hour in our buildings. And our new plant will be designed on the same criteria. Also, as Mr. Fath mentioned, the new plant will be in the south and consequently it is generally open-air construction. This is a problem in the plants in the north, because they are all constructed inside buildings.

MR. KLEIN: Is there some major problem involved in ventilation control, using ventilation as a control?

DR. LOBO: In terms of moving enough air to meet some lower level of VCM ---

MR. KLEIN: Yes, in terms of removing the monomer.

DR. LOBO: I think in some cases we are approaching infinity in terms of the amount of air we would have to remove to have an undetectable level. I think you can roughly calculate, maybe it is more academic--but one pound of VCM, if diluted with air uniformly would cover an area of 30 acres 15 feet high--and would equal one ppm.

MR. KLEIN: What technology in recent years have you used to control leaks better than you had previously?

DR. LOBO: We have upgraded our equipment, but we

haven't been able to really solve the problem. We have most recently used our ovameter to determine the flanges, pump-packing, compressors and so forth, which are leaking--and giving those more maintenance. We are looking at adding pumps which will not leak or leak at lower levels, evaluating different types of valves which we feel might leak less.

But this is a development program.

MR. KLEIN: Now, I understand that you have dramatically reduced the levels of exposurevery recently, is my understanding correct?

DR. LOBO: I don't think that was said.

MR. KLEIN: No, I have just heard that, I just want to know if that is an accurate understanding on my part.

DR. LOBO: We have made good progress, but I think we are talking about coming down from perhaps 200 ppm in some areas now where we are 25 and 30, which has allowed us to operate in those areas without the use of the respirators. We have been pleased with our performance, but it is a long slow job.

MR. KLEIN: Other than the controls, practices, etc., that you have indicated today, are there any other means used to reduce the level of exposure of employees?

MR. PATH: Well, of course, we have used respirators a good percent of the time and have put certain operations

on a standard respirator use procedure.

MR. KLEIN: How many hours a day do these employees wear the respirators?

MR. SCARITO: It varies, of course, with the jobs. It would range anywhere perhaps from five minutes for some employees to as high as perhaps an hour to an hour and 15 minutes at a time for other employees.

Is that what you meant?

MR. KLEIN: Yes. Now, at times when they are not wearing the respirators, are these employees in the ambient air that contains the vinyl chloride?

MR. SCARITO: What level of vinyl chloride?

MR. KLEIN: Any level.

MR. SCARITO: Well, yes, we have, as we have indicated before, there are measurable levels of vinyl chloride throughout the entire plant. And the employees are there.

MR. KLEIN: What level do you use as your cut off?

MR. SCARITO: Well, currently 50 is the cut off point at which we require mandatory use of respirators.

MR. KLEIN: Are there levels in your plant where the levels are below detectable level, as we define it in the proposal?

MR. SCARITO: Below no detectable?

MR. KLEIN: As defined in the proposal.

MR. SCARITO: I don't know of any area in the plant

that is below, that is zero VCM.

MR. KLEIN: How about one part per million?

MR. SCARITO: There are a few areas that we can measure at one to two parts per million, very few.

MR. KLEIN: Which areas are those?

MR. SCARITO: In general, they are the office most of the time, some of the outside areas, occasionally some of the warehousing areas, storage areas. These are the areas essentially where we find this low a level.

MR. KLEIN: Let's talk for a moment, if you will, about work practices that you have instituted which have improved--or decreased the level of exposure.

MR. PATH: Again, it would seem to me that the use of respirators and supplying additional ventilation, and a rather extensive measuring system throughout the plant by not only personnel monitoring, but organic vapor analysis, has helped us most to identify problem areas and to make actual corrections.

The big problem with personnel monitoring, when a high level occurs or a series of high levels occur within a low-level pattern, is the fact that these results come to us after the fact that these have occurred, and going back on those areas with organic vapor analysis equipment sometimes tends to identify the problem instantaneously.

And this is, of course, why the continuous

monitoring system is such an integral part of the proposal in that, from a time point of view, from a dosage point of view, it will do more to ring an alarm when a problem exists, permitting correction, than we feel any other part of the corrections that we can make.

MR. KLEIN: At what level have your monitoring devices been set to alarm?

MR. PATH: We do not have continuous monitoring installed in our plants at this point.

MR. KLEIN: Have you contemplated a level to have the alarm sound?

MR. PATH: Yes, we have. This would be the 40 part per million.

MR. KLEIN: Excuse me, I was referring to the monitors which detect the lower explosive limit. Have they ever gone off?

DR. LOBO: Yes, they have gone off a number of times, a good number of times being due to short-circuiting in the wiring. But they are set at 25 percent of the lower explosive limit. And to give an audible alarm. And then, at 50 percent, to turn on a deluge system which showers the area with water.

MR. KLEIN: Has it gone off because of vinyl chloride ---?

MR. SCARITO: Yes, we have had several occasions.

In each and every case--there have perhaps been four or five over the last couple of years, since we have had the installation complete--in every case it has been due to a specific accidental discharge of monomer. By accidental, I mean not a routine gradual buildup of monomer in the area, but rather a specific blown gasket or something of this nature.

MR. KLEIN: I would like to now direct your attention to monitoring, for a moment. Is there a hardship in monitoring the employees, a hardship for you people, the employer, in monitoring the employee rather than in monitoring the system?

MR. PATH: It is not a hardship, it is an additional operation which increases in complexity as you increase the number of samples. And we feel that the continuous monitoring system will do that for us automatically and will maintain much better records and will maintain a more complete, let's say, exposure under a time curve than the discontinuous personnel monitoring will do.

MR. KLEIN: Does the monomer disperse the air equally?

MR. PATH: I think it has been testified before, and we tend to agree with this, that it tends to disperse rather sluggishly and concentrates more around the area of primary leak than disperse very quickly into a vast mass of air.

Of course, the extent of ventilation and air movement then helps to diffuse it through a larger body of air.

MR. KLEIN: Is there some reason why continuous monitoring would be more accurate measure as to what an employee's exposure to vinyl chloride is than would a monitor that is on the employee?

MR. PATH: Yes, we believe so. If you just, for the sake of argument, assume a plant that has approximately 200 employees and one ten-minute sample per week would generate two hundred samples, and ten samples would generate, let us say, two thousand samples, this is not a hardship, it is just a lot of analytical work. And those ten samples, by way of example, would cover 100 minutes of that employee's presence of approximately 24 to 25 hundred minutes per week on the site.

The area, if monitored properly, will tell us what is going on in every one of the 2500 minutes, as an example of 42-hour week, of that employee's presence on that site and his movement through the various areas on the site.

MR. KLEIN: Now, on page 10 of the -- of Mr. Fath's testimony, you indicate these actions would take two or three years. The sixth line.

I am not sure I understand which actions you are talking about, to get to what level?

MR. FATH: The actions required regarding engineering solutions, design specifications, and purchase and delivery of the equipment in order to permit us to get to the tenth part per million time weighted average.

MR. KLEIN: On what basis do you say that it would take two to three years?

MR. FATH: Well, I believe we have delivery schedules of some of the vital pieces of equipment on hand, given to us by vendors, plus the normal installation times that are common to the industry.

I think our construction experience in Texas and in New Jersey indicates that these are normal kinds of constructing or constructing units, or modification of the plants.

MR. KLEIN: Do they indicate to you why there would be a to to three-year delay?

MR. LOBO: This is mainly due to a backlog of orders. We are in one of the biggest construction booms in the history of the country.

Some things are almost impossible to get. Three years

for some complex pieces of equipment is not unusual. 868

MR. PATH: I think I would like to modify the term "delay" here. I think these are normal in chemical construction. It is normal construction times. Delays would take us much beyond that period.

MR. KLEIN: Now, again directing your attention to page 10 of the testimony, you indicate that 100 parts per million unreacted monomer in the PVC by October of '77.

Could you tell us how you arrived at that date and the number, please?

MR. PATH: The basic number is an indication from current experimental work that we are doing. We feel rather confident that over a number of our resins would tend to reduce residual monomer content below that point, therefore setting a hundred as, let us call it, a specification type of content.

MR. KLEIN: Could you make those experiments, experimental data available to us?

MR. PATH: We can make the results available to you. The methods how we got to them we consider property of Tenneco.

MR. KLEIN: And now about the date, October of '77?

MR. PATH: Well, this coincides with the prior comment on delivery and construction schedules. If we need to make integral modifications in our plant, then we need to

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order additional equipment to achieve this on a routine basis across our entire, essentially our entire capacity, and therefore the date really relates to, again, engineering changes, to arrive at these levels.

MR. KLEIN: Now, on page 11, also the bottom of page 10, you indicate that the monomer does not travel once it is combined.

Have you done any testing of this question to see whether the monomer would come out of perhaps the reactive polymer, or some way be released?

MR. FATH: I believe what we said that once the monomer is chemically converted into polyvinyl chloride, that process is not reversible. The monomer physically retained in the polyvinyl chloride is of course subject to potential release.

MR. KLEIN: Let us talk about the levels that you recommend with respect to the PVC levels.

Where did you get those numbers from and those dates?

MR. FATH: The levels in the waiting zones in the PVC polymerization plants?

MR. KLEIN: Yes, sir.

MR. FATH: In a sense, those levels work backwards from the level of maximum feasibility that we have determined.

In other words, we are saying that we conceptualize

today in our plants, with our technology, if all our engineering concepts materialize, a ten parts per million maximum time weighted average level within two years.

The other levels of proposed are, in a sense, then interim levels between the present and -- and a period two years from now. They are interim for several reasons.

Some of the modifications necessary can be made prior to the expiration of the two-year period and will have a minor improvement effect.

The other significant element is that because of the weight we place on the continuous monitoring system, and there I know that we are in good agreement in that concept with other witnesses that have testified previously, we consider the continuous monitoring system necessary to tell us where we really are today.

Because while we can generate perhaps thousands of ten-minute samples per week, the generation of those samples has a minor influence on time weighted average considerations.

Only a continuous understanding of the levels that we actually have will permit us to finalize our corrections to be made to go down to the ten parts per million level.

MR. KLEIN: Let me ask you this: Is the basis upon which you state here today or recommend here today those levels, essentially the same basis that SPI had, that is, it seemed to be the consensus of those present at

the meeting that was discussed in their testimony, that that would be the level.

MR. FATH: Yes, it is.

I believe there is a common set of problems and therefore there is a consensus on the solutions to be applied to those problems.

MR. KLEIN: Would it be fair to say that you reached that same result as SPI, just based upon technical projection, sort of a judgment call, as it were?

MR. FATH: As a Tenneco judgment?

MR. KLEIN: Yes.

MR. FATH: As a Tenneco projection, yes, I think that is fair to say, and I think as part of the SPI group we have certainly made our views known, I am sure that our input was a part of the consensus consideration.

MR. KLEIN: What did you use as the point from which you projected?

MR. FATH: Well, as I stated before, the final point, and that is the ultimate, the lowest level we felt was practical to obtain --

MR. KLEIN: Excuse me. I would sort of define that as the point to which you projected. The point from which you projected. In other words, what facts and data did you project from in order to arrive at the conclusions that you apparently had arrived at?

MR. PATH: Well, the October 1974 date is reasonably close to the present, and as it relates to engineering improvements, that which we have not done to date, we will likely not then be able to do by October.

So we are using a general assessment of the current state.

I think it has been said before that the current state as of, let's say, June 1974, is a considerable improvement over conditions in January when we became aware of the problem.

MR. KLEIN: Now, I assume that there were PVC manufacturers who have levels that were considerably higher than yours, is that a fair assumption?

MR. PATH: On a personnel monitoring basis, yes, we have heard expressions from other -- from others that they had higher levels.

MR. KLEIN: Did this recommendation take into account the fact that these people have higher levels?

MR. PATH: No, it did not.

MR. KLEIN: Did it contemplate that some firms might not be able to get down to the level recommended?

MR. PATH: Yes, it did, certainly.

And I imagine that there might be testimony to that effect later on.

MR. KLEIN: I don't want to take the time of the

hearing now, but I would make a request to you: if you would, could you indicate to us the various job classifications and, as closely as you can, indicate what type, what the level of exposure is as to these job classifications, and whether it is an intermittent type exposure or a general exposure?

I really don't want to take the time of the hearing now, but I think that explanation would be very useful to us.

MR. PATH: I presume that these are the compliance records that we now have at our plants?

Let us say, cross-referenced by operator classifications?

MR. KLEIN: Yes, I think so.

If you could do that, we would appreciate it.

MR. PATH: Yes, we will make that available.

MR. KLEIN: Thank you.

Which job classifications are presently using respirators at your PVC plants?

MR. SCARITO: There, the reactor operators for certain short-term operations, are using respirators. People who unload our monomer from the rail cars to our tanks wear respirators. Our cleaners, our vessel cleaners wear respirators. Our maintenance people on certain specific jobs where they may come in contact with residual vinyl chloride, wear respirators.

I guess that covers it pretty well.

MR. KLEIN: In reducing the levels of exposure, from leakage of mechanical equipment, have other than what you have indicated in testimony, . is there any other type of equipment that you put in or contemplate putting in, that you would expect would reduce the level of leakage?

MR. LOBO: Not really. I think there are various types of valves, various types of pumps, various types of compressors.

Obviously we are evaluating what is available, trying to determine whether it would be an improvement over what we are using.

MR. KLEIN: Have you found any to be an improvement?

MR. LOBO: Well, the so-called can pumps could be an improvement. Some valves would be an improvement over what we are using.

MR. KLEIN: Now, on page 8 of your testimony, Dr. Lobo, you indicate that activated carbon is wholly impractical where there are large volumes of air and concentrations of VCM are involved.

Could you indicate why that is, sir?

MR. LOBO: The application that we are considering here is of the possible use of activated carbon to remove the VCM from the dryer out of it which has been mentioned not only in our testimony previously at the hearings. It

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is one of the major sources of contamination of the atmosphere.

Here we are looking at tremendously large carbon beds and very small concentration of VCM in the air, plus with air there is great concern about polymerization of the VCM on the carbon.

As I pointed out, even though there have been some claims that this was a panacea for the ills of the industry, we only have limited amount of data.

I must say that we haven't seen anything negative in the limited applications that we are looking at; that is where there is no air present.

But I don't see it as a practical solution to recovering VCM that might be present in only 100 to 200 parts per million, which is a general level in some of the dryer outlets.

MR. KLEIN: Would you be concerned that it wouldn't trap 100 percent of the monomer? Would that be a primary concern?

MR. LOBO: Just concerned that we are talking about very large piece of equipment, large pressure drops and [illegible] the problems of polymerization of VCM on the carbon itself.

MR. KLEIN: Have you done any experimentation in this area?

MR. LOBO: We have done some calculations to get some idea of the magnitude of the amount of carbon that might

be required.

MR. KLEIN: In situations where there is not a large volume of air with small concentration, where there is not a large volume of air but still there are small concentrations, would your view be different?

MR. LOBO: We feel that it is possible that this would do the job, and it is on this conclusion that we have installed this unit at Pasadena. I can report to you in five or six months whether our judgment was correct or not.

MR. KLEIN: I assume your judgment with respect to carbons to trap the monomer would apply equally to using carbon as a filter in the respirator; is that correct?

MR. LOBO: Yes, its action would be the same.

MR. KLEIN: Have you improved the efficiency of the recovery of the unreactive monomer in your plants?

MR. LOBO: Yes, we have.

MR. KLEIN: Is that process licensed?

MR. LOBO: We are improving this every day. We are not satisfied with our present achievements. We will need to add additional equipment to get what we feel is possible to get.

MR. KLEIN: What percentage of unreactive monomer do you have now?

MR. LOBO: It will vary between our plants, but generally the loss is between the three and four percent range.

MR. KLEIN: Is that a recent change or has that been the number more than six months?

MR. LOBO: This, I don't recall the exact numbers, but I say in some plants it has been an improvement of perhaps two or three percent over the last six months.

MR. KLEIN: Is the process by which you reduced the unreactive monomer a licensed process,, or can you tell us how you did it?

MR. LOBO: It is just [illegible]ng good engineering principles. I think the knowledge is available to the industry. It just takes time to implement it.

MR. KLEIN: Do you know how, when you make a design specification, how you would project as to what the level of exposure would be after it was implemented?

MR. LOBO: This is a -- merely a judgment, since we have never operated at the lower levels, we really don't know whether we can get there or not until we are there. A very subjective thing.

MR. KLEIN: Returning just for a moment back to the unreacted monomer, have you found that in reducing the unreacted monomer that the resins that have resulted have been less useful further on down the line, or have they kept essentially the same qualities?

MR. LOBO: It depends how we do it. We have hurt the qualities of the resin by some of our experiments.

Other times we have been more successful.

MR. FATH: I think the distinction might be made here between the lowering of residual monomer contact in the resin and a lowering of losses across the plant.

In one case we are talking about lowering in terms of parts per million. In the other case we are lowering the lack of accountability, if you wish, of the loss in terms of percent numbers.

So the problems are not necessarily the same.

MR. KLEIN: On page 12 of your testimony, again you have indicated that certain employees in certain job classifications are required to wear respirators part of the time, and that you believe that that percentage of time represents the tolerable maximum.

No. 1, was the answer given before now represent what you were talking about there, tolerable maximum?

MR. LOBO: Yes.

MR. [illegible] On what basis do you conclude that one hour is the tolerable maximum?

MR. LOBO: This particular judgment is based on the comments made by Mr. Scarito as to the problems involved in wearing respirators and these are real in our plants. Whether it is the one hour or not.

MR. FATH: Again, Mr. Klein, I think we ought to distinguish between Mr. Scarito's comment that related to

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the present. One hour, one hour and a quarter. The present condition. We are not currently at the ten parts per million maximum referred to in Dr. Lobo's testimony.

In other words, we would expect the incidence of respirators to go up materially when we go down to the ten parts per million maximum.

MR. Klein: Do you have any recommendations as to maximum amount of time throughout an eight-hour day that the employee should be allowed to wear a respirator? Should be required to wear one?

MR. FAITH: We have no specific numerical recommendations.

MR. Klein: Mr. Scarito, have you performed any tests with respect to employees' hearing ability while wearing the full-face respirator?

MR. SCARITO: I don't know whether you would formalize it by calling it a test or not, but I have worn them myself. Many of our staff people have worn them to determine how readily they were able to see and operate and manipulate and so forth, and it's obviously quite restrictive. I can't put a number on it, but there's no question about it.

MR. [illegible]: So then your statement about respirators are based on your observations, then?

MR. SCARITO: Personal observations, mine and others.

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MR. KLEIN: On page 5 of your testimony, you talk about taking siding from the building. Made to wear respirators.

Could you tell us how that works?

MR. SCARITO: Well, what we have tried to do is approach an outdoor plant, where practical, and improve ventilation by taking off sections of the siding.

MR. KLEIN: Thank you, Mr. Scarito, I have no further questions.

MR. KUCHENBECKER: One question I would like to direct to the panel.

From the standpoint of the number of workers exposed to vinyl chloride at your various plants, could you give me a rough idea of the number, the rate of employee turnover at the various production stages?

MR. FATH: Our particular turnover history?

MR. KUCHENBECKER: Yes, perhaps in the last two or three years.

MR. FATH: Well, of course, we have those data and we don't have them with us, but --

MR. KUCHENBECKER: Could you make those available?

MR. FATH: It is likely that perhaps a third of our workforce is in the zero to five year category. Perhaps somewhere between a third and forty percent.

MR. KUCHENBECKER: All right, thank you.

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MR. LASSITER: I have a couple of questions I would like to ask Mr. Fath first.

You mentioned that in your experience with employee deaths, you had about 20 deaths out of 1,000, none of which were attributed to angiosarcoma.

Do you feel that this finding is of a statistical significance when compared to the experience of the risk of angiosarcoma in the male population or the adult population of the United States?

That is, this number of risk compared to what we normally see about 25 per the U. S. population?

MR. FATH: If I understand your question, Dr. Lassiter, we're saying that we have had no such deaths out of our population of 1,029?

MR. LASSITER: Yes, I am wondering if you consider this a statistical significance in view of the rate that we normally see in the United States that has been reported?

MR. FATH: I would suspect that both the number zero and the number 1,029 are too small in making any statistical conclusions.

We are simply stating the fact that in that worker population, our operation has not experienced any of these deaths.

MR. LASSITER: Thank you.

I was particular interested by your testimony as

opposed to area monitoring.

Would you feel that perhaps that area monitoring, backed up by personal monitoring, would be something that would be giving a picture of individual exposure? Realizing that the point that you raise, that perhaps area monitoring, if properly applied, can do this; but do you feel that perhaps personal monitoring may be required to establish this type of area monitoring before it can be relied upon?

MR. FATH: If I may reply to the question and perhaps a period of time in which area monitoring would be backed up by personal monitoring, and perhaps the burden of the person monitoring might be phased out if there is satisfactory data available, that the two indeed coincide in what is represented as an exposure in the plant, then I certainly see no harm in accumulating additional data.

I would hope that with enough experience in the monitoring, in the area of monitoring work, that it can be demonstrated that immediately or eventually that personnel monitoring is redundant and that therefore that particular analytical chore might be removed from the plants.

MR. LASSITER: Do you feel that at any time you can completely rely upon only area monitoring?

MR FATH: We would expect that to be true, but of course not having any direct experience, I don't think that we could make that statement here today.

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MR. LASSITER: In just a point of clarification, do you consider a safe threshold the same as a widely acceptable risk threshold? Is this one and the same, or are we talking about two different thresholds here?

That is, a safe threshold as opposed to a widely acceptable risk threshold?

MR. FATH: I think the two concepts are alternate concepts.

The most desirable, of course, would be to establish a safe threshold in which one can have scientific confidence.

MR. LASSITER: Would you have anything that you could tell us about what would constitute a widely accepted risk threshold as to who this would be acceptable to, for example?

MR. FATH: Well, I think that is really the key of these deliberations here. I would expect that the Secretary's [illegible] decision in this matter, will represent the widest publicly accepted risk threshold when that decision is finally made.

MR. LASSITER: You would leave this decision to the government and expect the government to make this type of decision; is that correct?

MR. FATH: Given the input that we are providing at this point, yes, I think that is the --

MR. LASSITER: Then you would have no guidance to

give as to what you consider a widely accepted risk threshold, is that correct?

MR. PATH: Well, the guidance that we have given represents one of maximum feasibility and we have given that in the unfortunate absence of conclusive data which I believe all interested parties concur. The fact that conclusive data are unfortunately not with us in the timespan required to make decisions

MR. LASOFSKY: I am not going to push this point, but I would like to see if you would be able, or feel that you can in any way give us some information about what you consider an acceptable risk, and I assume here we are talking about a risk of contracting angiosarcoma.

MR PATH: We are not in a position to do that.

MR. LASOFSKY: Thank you

MR. KLEIN: Thank you very much.

JUDGE MYATT: I was beginning to wonder if there would be any questions left for the rest of you to ask, but I am sure you will surprise me and find a few.

Yes, sir, step up.

MR. CLARK: Dennis Clark of the United Steel Workers.

JUDGE MYATT: You are going to have to speak into that mike.

MR. CLARK: Dennis Clark, counsel for the United

Steel Workers of America.

I will address this question to Mr. Fath, although he could defer to any member of his panel if he deems it appropriate.

In your various testimony you described your efforts to reduce exposure levels in your existing facilities and also, I believe, you described in your new plant that you are building in Texas.

You made mention of various licenses or trade secrets involved in various technological advances in reducing its exposure levels, is that correct?

MR. FATH: That refers primarily to our new plant which we have the technology, for which we have licensed from the Shinitzu Company in Japan.

MR. CLARK: Licensed from what other company did you say? Or are you the licensor?

MR. FATH: We are the licensee. Licensed from the Shinitzu Company in Japan.

MR. CLARK: I see. Are there --- are those types of license available for the rest of the industry also?

MR. FATH: Yes, they are, to the best of our knowledge.

MR. CLARK: Thank you.

JUDGE MYATT: Yes, sir?

MR. SAMUELS: Mr. Fath, has your company conducted

any technical studies? That is to [illegible] existing employees and former employees?

MR. FATH: Yes, we have [illegible] given the medical examinations as [illegible] within recent weeks to our employees.

MR. SAMUELS: Do you have [illegible] time to give us or --

MR. FATH: We do not [illegible] time, but the results are being [illegible] examining authorities.

MR. SAMUELS: And I presume [illegible] to the Government [illegible] this location?

MR. FATH: That is [illegible] are employed.

MR. SAMUELS: I believe you said that you needed, in order to reach ten parts per million at the plant, two years; is that correct.

MR. FATH: That is correct.

MR. SAMUELS: Is there no difference, then, between the ability to meet this goal by the location and age of the plant?

MR. FATH: If I understand the question correctly, Mr. Samuels, the newest plant currently under construction, I've indicated, might be able to meet that standard before the

two years. However, we will only know that once we operate.

MR. SAMUELS: But in general you would expect that newer plant in the south, where they might be open, open plants might be of a year's period of time?

MR. FATH: Not wishing to speak for other technologies, I don't think you can necessarily draw that conclusion because while that location favors lower levels, the quality of the engineering and frankly the type of the product produced, also has considerable influence.

Let me add there that as I indicated, we manufacture some 36 different resins. Our new plant in Texas will produce only three of these types.

Therefore, other technologies, whether they are located north, south, or elsewhere, are not subject to the same engineering skills and improvements as that particular plant is.

MR. SAMUELS: I see. But in general you would, would you subscribe to the concept that the fewer the reactors, the larger the reactors that might be outdoors, plus supplying reactors with monomer by pipeline, these are factors which reduce and make more feasible the reaching of any level.

MR. FATH: That is indicated, yes.

MR. SAMUELS: I have a question for Mr. Lobo, but

perhaps you might want to refer to someone else in your panel.

I referred to you because you mentioned that the capital expenditures would be $10 million.

Is this for all plants plus the contemplated expansion in Pasadena?

MR. LOBO: Yes, this is our very preliminary guess, what the capital requirements might be to reach the ultimate level that we can get to by 1976.

MR. SAMUELS: So it is not based on a hard cost data?

MR. LOBO: That is correct.

MR. SAMUELS: Okay.

Now, you have broken this down by plants, or you just had a gut feeling that it was all the plants involved?

MR. LOBO: No, it has been broken down by plants, again, based on our best estimate at this time.

MR. SAMUELS: Given the current price of resin, I don't know what you charged, big. Yesterday, one of the fabricators said he was paying 35 cents a pound. Can I ask you currently what your prices are?

MR. FATH: Certainly. I believe the reference yesterday to 32 cents a pound was referred to plasticol for resin, which is of a different type and more costly to produce.

Our general-purpose resins, our current price is 17 cents a pound.

MR. SAMUELS: Now, looking at this $10 million capital expenditure, and I realize that there are other costs, labor costs, et cetera; looking at it, could you calculate this cost as a percentage of the sales price of the resin which you just established -- did I hear you right -- you said 17 cents?

MR. FAITH: Yes.

MR. SAMUELS: What percentage of the sales price would this capital expenditure constitute, roughly?

MR. FAITH: I believe it can be calculated, but it depends on how many pounds.

MR. SAMUELS: How many pounds do you --

MR. FAITH: I don't think one can come up with any single percentage figure.

Let us also recall here, the ten was upward of ten. We are not currently sure that that particular number is a high enough number. It is an order of magnitude number that we are quite convinced will not go below; we may go substantially above.

MR. SAMUELS: Would you hazard a guess about a range?

MR. FAITH: That is entirely dependent upon the final standards that will be issued, because that number and any

range associated with it relates to our final number of ten parts per million.

MR. SAMUELS: That is right. I mean, given the ten parts per million, I am trying to find out, get a feel for what this costs.

MR. PAGE: The ten might be twenty.

MR. SAMUELS: The ten might be twenty?

MR. PAGE: Yes.

MR. SAMUELS: And if it were $20 million, you wouldn't want to supply for the record what percentage of the sales [illegible] that might be?

I will be very specific as to why I am asking [illegible] there is another Arthur D. Little report, [illegible] EPA document called Economic Analysis of Proposed Effluent [illegible] for the Plastics and Synthetics Industry.

[illegible] page 58 of that study, there is an interesting conclusion where they try to calculate the cost of meeting [illegible]. They would be left in the percentage of sales of only 1.3 percent. They said, "We believe" -- I am quoting -- "that this would not have any impact on the industry."

[illegible] of course we are trying to find out whether the cost of control, for ten parts per million or one part per million would be in that neighborhood.

Do you have any thoughts?

MR. FATH: Well, nowheres in our testimony--and I would like to reiterate this--have we been guided by those economic considerations. That is to say, we believe in investing the necessary funds to reach the most feasible--the lowest feasible level.

So, we have not taken that consideration into account in coming up with lowest technologically feasible levels.

MR. SAMUELS: Thank you.

MR. COTTINE: Mr. Fath, do I understand your testimony correctly that there is a new facility under construction and another facility under expansion, or is there only one facility that is being developed?

MR. FATH: There is only one facility under construction.

MR. COTTINE: And that is the Houston facility?

MR. FATH: Yes.

MR. COTTINE: When did your engineering planning commence for that particular facility? The year.

MR. FATH: I believe it was 1972.

MR. COTTINE: When was the design and operational program completed? In other words, that study and final plans completed.

MR. FATH: Well, we broke ground in August of last year, 1973.

MR. COTTINE: August of '73. Did you make

any modifications on the basis of the old Maltoni experimental data as to the control techniques that you would use with respect to this VCM?

MR. PATH: Well, as I indicated, we would expect to meet the 10 ppm maximum in the operation of that plant within a reasonable time. Since those levels are so considerably below anything either the Viola or the Maltoni studies showed at that time, that was not a vital consideration.

MR. COTTINE: So, you did not consider the studies at that time and no modifications were made; is that correct?

MR. PATH: At that time the state of knowledge was such that the 450 ppm level was the lowest one.

MR. COTTINE: If indications were such at 10 ppm there was a carcinogenic response, would that prompt a renewed consideration of the controls there?

MR. PATH: If I understand you, if that had been at the time we probably wouldn't have gone and expanded our business.

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MR. COTTINE: How has your monitoring progressed over the past two or three years? Has it been in steps, or what would you consider the milestones?

[Continued on page following.]

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This is monitoring sensitivity.

MR. PATH: Yes, of course we have only instituted the personal monitoring since the issuance of the temporary standard, so we don't have a two to three year history.

The general history that we have is somewhat qualitative in nature. Using oder levels as an order of magnitude, and I guess we have heard a lot of discussion on that subject, we have had essentially no oder levels in our plants in many recent years that we have operated.

MR. COTTINE: So any sensitivity would be based just exclusively on the oder level. You can't describe your monitoring process from 250 parts per million down to 50 parts per million or the like?

MR. PATH: Not -- not backwards of the first part of this year, that is right.

MR. COTTINE: Was there some period? I asked in two or three years. Was there a period there there is a breakthrough?

MR. PATH: No, we cannot tell you.

MR. COTTINE: All right.

Someone on the panel discussed the fact that there were levels of VCM in the office. What was the highest level, and what are the average levels that you found in those office sites?

MR. SCARIMO: I believe that was part of my

testimony.

The average levels, I would say, run between one and two. The highest level that I can recall seeing there would be about seven or eight, perhaps nine. Very occasionally -- that's about all I can tell you.

MR. COTTINE: Okay, that is one or two ppm?

MR. SCARITO: Yes, that is correct.

MR. COTTINE: Have your facilities been inspected by any governmental agency for vinyl chloride exposure within the past six months?

MR. FATH: OSHA.

MR. COTTINE: OSHA for perhaps local enforcement authority?

MR. SCARITO: Yes, we were inspected on June the 10th and 11th.

MR. COTTINE: By OSHA?

MR. SCARITO: By OSHA.

MR. FATH: Also by EPA.

MR. COTTINE: By EPA?

MR. FATH: Yes.

MR. COTTINE: I assume that both of those inspections involved VCM monitoring, is that correct?

MR. FATH: Yes, that is.

COTTINE: What were the results of that monitoring conducted by these two agencies?

In terms of levels.

MR. FATH: Right. The EPA data, I don't believe are published as yet.

MR. COTTINE: You haven't received it?

MR. FATH: No, our informal understandings are that the parimeter lines are one part per million or below. We do have the data for our Pasadena monomer, they are on the order of .3 parts per million.

MR. COTTINE: And the OSHA inspection, have you received the sample data sheets back on those?

MR. FATH: No, we have not We have had extensive inspection of our own data and records.

MR. COTTINE: I assume in response to the other response, it will be submitted for the record?

MR. FATH: Certainly.

MR. COTTINE: Would you also submit the OSHA and EPA monitoring levels?

MR. FATH: We will be glad to when they are received.

MR. COTTINE: Obviously you have a monitoring program. Do you have a medical surveillance program?

MR. FATH: We do.

MR. COTTINE: Have you established any ppm levels or goals recently, since the establishment of the emergency temporary standard?

MR. FATH: Well, we certainly established the emergency temporary standard as an operational procedure. If I understand your question.

MR. COTTINE: Okay. And therefore what was your goal prior to that time?

MR. FATH: I don't believe we addressed ourselves to that particular problem of goal prior to that time. Since the goal was not set for us.

MR. COTTINE: Now, with respect to the medical surveillance program, how did you employ the experimental data on the carcinogenicity of vinyl chloride in the medical surveillance protocols that you developed, or did you?

MR. FATH: We did not develop our own protocols, but are rather following the protocols established in the standards.

MR. COTTINE: So you have no medical surveillance protocol prior to the standards?

MR. FATH: I didn't say that. And I don't think you asked that.

I think you asked, if I understood it, how we developed the current medical surveillance protocol.

And that was on the basis of the guidance we received from the published protocol.

MR. COTTINE: All right, now prior to the adoption of the emergency temporary standards, you did have a medical

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surveillance protocol, did you not?

MR. FATH: We had medical examinations for employees that came on board, and you might call it the ordinary physical examinations that are consistent with industrial hygiene practice, not addressing itself to this special problem.

MR. COTTINE: Okay, so, in summary, then, you had a medical surveillance protocol, but it was not specific to liver dysfunction amongst the workers whowere exposed to VC?

MR. FATH: That is correct.

MR. COTTINE: Would you submit your current medical protocol for the record?

MR. FATH: Well, we would be glad to, but I think it would be a duplication of that which is in print, since it is, in fact, no different than that which has been published.

MR. COTTINE: I think it would be helpful just to see what the protocol was.

JUDGE MYATT: Go to your next question, Mr. Cottine.

MR. COTTINE: How many Tenneco plants will be covered by the OSHA permanent standards for VCM?

MR. FATH: That depends upon the final complexion of the standard. We will have three plants for VCM and PVC manufacture. We have another three plants for vinyl processing, and depending on the outcome of the deliberations

in line with the suggestions for proposals to eliminate these, it will either be three or six.

MR. COTTINE: Okay. How many of these plants will be forced to close down if the proposed standard is in fact adopted by the Secretary of Labor?

MR. FATH: Well, as I indicated in the options that we have, if we close down the three resin plants, then the three processing plants would be closed down for lack of product.

MR. COTTINE: But if you could otherwise be supplied PVC resins, your other plants could comply [illegible] with the proposed standards?

Let me rephrase that.

If you had a supply of PVC resins --

MR. FATH: Without manufacturing --

MR. COTTINE: Right, would your other plants still be capable of complying?

MR. FATH: I believe so.

MR. COTTINE: Fine, thank you.

JUDGE MYATT: Any other questions?

[No response.]

JUDGE MYATT: Thank you, gentlemen.

The Dow Chemical people, I told you that I hoped that we would get to you. I seriously doubt it.

This was scheduled for an hour, and it took roughly

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STATEMENT FOR OSHA HEARINGS ON VINYL CHLORIDE

June 27, 1974

From: Richard R. Monson, M.D.
John M. Peters, M.D.

Of: Harvard School of Public Health
Boston, Mass.

We have information on deaths from two plants in which vinyl chloride monomer is produced and in which poly-vinyl chloride is made. Our data overlap somewhat with that of the CDC and HCA (Tabershaw & Cooper, Manufacturing Chemists Association). But we wish to stress two points (1) multiple cancer sites are involved and (2) cancer is increasing over time in this population.

From death information certificates, 161 deceased white males from these two plants were identified. For all but nineteen, a copy of the death certificate was obtained. For the remainder, the cause of death was gotten from company abstracts. Deaths from 1947 through 1973 were ascertained.

The observed cases were tabulated. The expected cases were derived from data on U.S. white males based on age, time and cause.

A 50 percent excess of deaths due to cancer was found. The observed number of liver cancer cases was 10 times expected. This is not a new finding. There was a 60% excess of lung cancer (13 cases with 7.9 expected), and a 320% excess of brain cancer (5 cases with 1.2 expected). Suicide was also excessive (10 cases with 5.3 expected).

The time trend is also alarming. Cancer experience in this population before 1965 was almost as expected (12 cases with 11.4 expected). Between 1965 and 1969 there was a 40% excess (10 cases with 7.3 expected).. Since 1970 there have been 19 cancer deaths with 9.2 expected (a ratio of 2.1).

This proportional mortality analysis does not allow the calculation of cancer rates. It is possible that this group of workers does not suffer a greater overall mortality than the general population. The excess of several specific cancers plus the time trend suggest a causal link between occupational exposure to vinyl chloride and cancer.

I do not believe we will know the full cancer causing potential of vinyl chloride for several years. At this point the only way to assure an end to this serious hazard is to eliminate exposure.

Table 1. Observed and expected deaths in vinyl chloride workers.[a]

ICD number[b]	Cause of death	Observed	Expected	Obs/Exp
—	All	161	161.0	1.0
140-205	All cancer	41	27.9	1.5
150-159	Digestive	13	8.3	1.6
155	Liver & biliary tract	8	0.8	10.0
162, 163	Lung	13	7.9	1.6
193	Brain	5	1.2	4.2
200-205	Lymphatic & hematopoetic	5	3.4	1.5
—	Other[c]	5	7.1	0.7
330-334	CNS vascular	8	9.5	0.8
400-468	Circulatory	66	68.6	1.0
800-998	External	22	24.5	0.9
960-969	Suicide	10	5.3	1.9
—	All other[d]	24	30.5	0.8

a Expected numbers based on age-time specific proportional mortality rates for U.S. white males

b International Classification of Diseases, 7th Revision

c Nasopharynx - 1, prostate - 1, kidney - 1, thyroid - 1, undetermined - 1

d Includes 2 cirrhosis (4.2 expected)

Table 2. Observed and expected cancer deaths in workers according to age and year of death.

Characteristic	Category	Observed	Expected	Obs/Exp
Age at death	<50	11	7.6	1.4
	50-59	17	8.1	2.1
	60+	13	12.2	1.1
Year of death	<1965	12	11.4	1.1
	1965-69	10	7.3	1.4
	1970+	19	9.2	2.1

causing potential of vinyl chloride for several years. And while no future projections can be made with certainty, additional excess cancer among vinyl chloride workers may reasonably be expected.

At this point, the only way to assure an end to this serious hazard is to eliminate expos[illegible] Thank you.

JUDGE MYATT: All right, Mr. Klein.

MR. KLEIN: Dr. Peters, have you provided the underlying data for your projections that you have made and the statistical information you furnished?

DR. PETERS? Yes, that was in the report I submitted to the Judge.

MR. KLEIN: Unfortunately, we have not had an opportunity to look at that.

Do you consider 161 to be a number that is statistically meaningful in its relationship to the overall vinyl chloride hazard?

DR. PETERS: In this case, it certainly is. It revealed what was known to be a problem already, the angiosarcomas, and also suggests at least two other sites as having excess cancers, brain and lung.

MR. KLEIN: In terms of the numbers, the 161, do you consider that that is a statistically significant number in terms of the overall hazard?

DR. PETERS: It is not really possible to call that a

statistically significant number.

I think when you have 8 cases of liver cancer with .8 expected, and when you have 5 brain cancers with 1.2 expected, that is significant.

We did not do statistical tests on these data because the statisticians considered that they were meaningless.

MR. KLEIN: Which two plants were involved in this?

DR. PETERS: These were two B. F. Goodrich plants in Kentucky.

MR. KLEIN: Are they near each other?

DR. PETERS: Yes. Well, I am not sure how far apart they are. I think they are quite near each other.

MR. KLEIN: Have you done any studies at plants where they have been no known deaths of angiosarcoma?

DR. PETERS: This is the only population of workers that we have looked at exposed to vinyl chloride.

MR. KLEIN: Mr. Lassiter has some questions.

MR. LASSITER: As far as your testimony, I did read it prior to your giving it here.

What was the source of your data, you mentioned B. F. Goodrich plants. Was it done by yourself or from another source?

DR. PETERS: It came through, primarily through the B. F. Goodrich. They were supplying us death certificates

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DR. PETERS: That is true.

MR. HECKMAN: And how long have you been at this, by the way, this particular study?

DR. PETERS: Well, we have been studying rubber workers for quite a long time, this particular study --

MR. HECKMAN: This doesn't involve rubber workers.

DR. PETERS: This particular study was commenced in -- the end of February, I believe.

MR. HECKMAN: Of this year?

DR. PETERS: Yes, sir.

MR. HECKMAN: You have been working on this questionnaire sampling activity since the beginning of February of this year?

DR. PETERS: On this particular study.

MR. HECKMAN: And this study related to comparing number of population at the Goodrich plant with number of deaths, and relating it in some way to population elsewhere?

DR. PETERS: We looked at the dead people from these two plants, and prepared the proportion of deaths to expected portions of death in U. S. white males.

MR. HECKMAN: Nationally?

DR. PETERS: Yes.

MR. HECKMAN: Did you do anything regionally?

DR. PETERS: No.

MR. HECKMAN: Are you familiar with the fact that

at one time there was a hepatitis epidemic in the area in question?

DR. PETERS: No.

MR. HECKMAN: Do you think that might not have a bearing on the situation at all?

DR. PETERS: I don't think so, but it might.

MR. HECKMAN: And, as I understand it, you considered a figure, 161, statistically significant?

DR. PETERS: There is no way about talking statistical significance of a number, I don't think.

MR. HECKMAN: It has been done here for the past two or three days. Have you been present during some of these hearings?

DR. PETERS: Yes.

MR. HECKMAN: And you have heard that term used, haven't you?

DR. PETERS: Right, but not on a single number.

MR. HECKMAN: If I understand your testimony correctly, you are saying that by looking at the Goodrich deaths and comparing it with the Goodrich population and then comparing that with the national average for white males, you come up with a horrendous figure of growth in cancer, and you are willing to project that into a major concern, is that correct?

DR PETERS: I think you made one misstatement.

We are looking at deaths from these two plants. We do not know about the denominator populations, and we are comparing the proportions again, the proportions expected versus the proportions seen and we see excesses of cancer only.

MR. BECKMAN: And you have had, you began this study in February and you did not think it necessary to consider other plants or locations including other plants where there may have been deaths in order to come up with your conclusions?

DR. PETERS: We did not have access to other death certificates from other vinyl chloride plants.

MR. BECKMAN: Did you attempt to get any?

DR. PETERS: No, we didn't.

MR. BECKMAN: Did you attempt to get any data from plants where there were no deaths?

DR. PETERS: No, we didn't.

MR. BECKMAN: Do you consider this a valid scientific study?

DR. PETERS: Of course I do.

MR. BECKMAN: On what grounds?

DR. PETERS: On the grounds that proper epidemiological methods were used, and the -- well, that is enough.

MR. BECKMAN: Well, unless I misunderstand, proper epidemiological grounds includes the need for statistically

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DR. PETERS: Harvard.

MR. TOPOL: And how many people worked on it?

DR. PETERS: I would say that -- a total of three or four depending on how you count it. There were clerks collecting death certificates, and to this end, the work was primarily done by Dr. Monson.

MR. TOPOL: By yourself or just by Dr. Monson?

DR. PETERS: Almost entirely by Dr. Monson.

MR. TOPOL: How much time would you say Dr. Monson devoted to this project in terms of hours?

DR. PETERS: I couldn't estimate that.

MR. TOPOL: Is it a two-week project or what in terms of hour time?

DR. PETERS: I really couldn't say.

MR. TOPOL: You made your study based on the -- I think you said the Goodrich plant in Louisville, is that correct?

DR. PETERS: And Calvert City.

MR. TOPOL: At the time you began that study, were you aware of the fact that there had been angiosarcomas reported among employees at that plant?

DR. PETERS: Yes.

MR. TOPOL: How many were you aware of at that time?

DR. PETERS: I am not sure whether it was three or

four.

MR. TOPOL: At least when you began that study, wasn't it perfectly clear to you that you would end up with more angiosarcomas among those employees than the population as a whole?

DR. PETERS: Yes, that is not one of the major things that I wanted to stress today, that is well known.

MR. TOPOL: Okay. If you took any of the other plants in the United States, twenty years or older, which have not had any angiosarcomas among their employees, what conclusion would you draw from that fact?

Would you -- would that support the conclusion that vinyl chloride does not cause angiosarcoma?

DR. PETERS: I wouldn't be willing to make that conclusion on what you just proposed.

MR. TOPOL: If, in view of your conclusion that angiosarcoma -- that vinyl chloride exposure was the cause of the angiosarcoma among those employees, how do you explain the fact that there are eight polyvinyl chloride polymerization plants in this country twenty years or older which have not had a single case of angiosarcoma?

DR. PETERS: Well, I think there are several factors. One, of course, is the dose, the level, and when the dose occurred, the average duration of exposure to the workers involved, they would be two major considerations.

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MR. TOPOL: The dose and age of the exposure?

DR. PETERS: The length of the exposure, yes. It is possible to have a twenty-year-old plant with high turnover and nobody stays there twenty years. I don't know the situation well enough to comment on the other eight plants.

MR. TOPOL: I see, but, on the other hand, if the exposures of the other eight plants were lower than the exposures to the plants that you dealt with, then could you and employees have been exposed for long periods of time, couldn't you then draw the conclusion that the levels of exposure to those eight plants were safe levels in terms of angiosarcomas?

DR. PETERS: I am not sure that I would be willing to do that at twenty years, but it would certainly suggest that --

MR. TOPOL: That it might be the case?

DR. PETERS: Yes.

MR. TOPOL: One final question.

You made, for purposes of your general population, comparison, the white males throughout the United States. Isn't it a fact that your norm would have been different had you used as your base the industrial employees in the United States?

DR. PETERS: Yes, I think the results would

probably have been more dramatic.

MR. TOPOL: What is the difference between the white male base norm and all industrial employees, that you know?

DR. PETERS: Yes, in general, in doing mortality studies in industry, you are looking at lower mortality rates than from the general population.

MR. TOPOL: And do you have any written data, or is that going to be supplied to -- as part of the record in terms of the work? Was the only data the death certificates -- I guess, were there any examinations by your people?

DR. PETERS: It is death certificate information.

MR. TOPOL: So then essentially you are saying that you drew numerical conclusions based on death certificates from the Louisville plant?

DR. PETERS: Yes, sir.

MR. TOPOL: Thank you.

MR. CONNOLLY: Did you obtain death certificates from everybody who has died in both of these plants?

DR. PETERS: By company records, we obtained death information on everybody who had died.

MR. CONNOLLY: You indicated earlier in your testimony that Goodrich had sent you certificates for all their plants. Was I wrong in hearing that?

DR. PETERS: I think that that is right.

MR. CONNOLLY: You had death certificates from all the plants? 913

DR. PETERS: Yes.

MR. CONNOLLY: Not just these two. Why weren't the other vinyl chloride plants included in your study?

DR. PETERS: I think they at that point, we knew about the -- we were apprised of the angiosarcoma in Louisville. We had the population of death certificates coming from Kentucky, and we looked to see what we would see, and this is what we saw; and we later confirmed that they were from the two plants in question.

None of the other plants were, I am not sure about this, Dr. Monson can answer this, but I think none of the other plants, there were enough deaths to do studies on. They were smaller populations and fewer deaths.

MR. CONNOLLY: Were the other plants not statistically relevant, is that what you are saying?

DR. PETERS: That is the decision made by Dr. Monson, yes.

MR. CONNOLLY: And if they were not statistically relevant, are you saying that these two plants are statiscially relevant?

DR. PETERS: Yes.

MR. CONNOLLY: Do you know the difference in the numbers? You say in the other four B. F. Goodrich plants

there were less deaths than the 161 you found in these two plants?

DR. PETERS: I do not know the numbers.

MR. CONNOLLY: Did you follow the deaths of those people who left the company?

DR. PETERS: These are the -- all of the people who were employed by the company who died, by the company's records.

MR. CONNOLLY: What about the people who resigned or retired? Were they not included in your study?

DR. PETERS: They were.

MR. CONNOLLY: B. F. Goodrich tracked down every person that retired, quit the company?

DR. PETERS: These were -- I am sorry, these are retired and pensioned people.

MR. CONNOLLY: It does not include those people who resigned after ten or fifteen years of service?

Is there any particular reason, other than the fact that the other four plants did not have the statistical representative cohort to include in the study, and that was the only reason that you did not include them in the study?

DR. PETERS: Dr. Monson made that decision and I think that is true.

MR. CONNOLLY: Now, when you compare workers who have died, to the white male population, do you include in

the white male population children, babies who are born and die?

DR. PETERS: No, we include only those people who are the same age, sex, race, and the time that the person died.

For example, if somebody died in 1945, we would use the death rates for 1945, for somebody of that age to develop our expected proportions.

MR CONNOLLY: If B. F. Goodrich perchance had another plant in the area, relatively the same area that had a statistically number of deaths, but they were not in the polyvinyl chloride business, could you have compared the statistics you obtained from B. F. Goodrich in the polyvinyl chloride end of the business to the non-polyvinyl chloride business? Would that not have been more representative than comparing your statistics to the over-all white male population?

DR. PETERS: That might have been better had we known the conditions at the other plant.

MR. CONNOLLY: Did Goodrich send you any death certificates from their Avon Lake plant?

DR. PETERS: I believe we have some.

MR. CONNOLLY: Is that plant approximately thirty years old?

DR. PETERS: I don't know.

MR. CONNOLLY: Let me suggest to you it is thirty years old, and are you telling me that for some reason you and your cohort, who has chosen not to show up here today, decided to exclude those deaths from the Avon Lake plant from your study?

DR. PETERS: That is true. I think there were not very many deaths in that plant.

MR. CONNOLLY: You indicated there was an excess of lung cancer you found in these -- in the populations that you studied. Did you go into the smoking history of those people who died?

DR. PETERS: No, sir.

MR. CONNOLLY: Is there any correlation between lung cancer and perhaps brain cancer, to your knowledge?

DR. PETERS: There could be in terms of spread to the brain from the lung.

MR. CONNOLLY: And if in fact someone had developed lung cancer because of smoking, could that have been responsible for the brain cancer?

DR. PETERS: It could have been, although we saw, I think, four primary -- meaning that they originated in the brain, brain tumors.

MR. CONNOLLY: So, having not looked into the lung cancer cases, to determine whether or not there was any smoking involved in the individuals that you studied, you

really can't draw any conclusions, valid conclusions from those facts, can you?

DR. PETERS: Well, as I mentioned, I think that it suggests that there is a problem with the lung and the brain, and I think they were the words that I used.

MR. CONNOLLY: You suggest --

DR. PETERS: With an epidemiologist study I don't think that you can prove cause and effect, but you can certainly get leads for problems.

MR. CONNOLLY: But you certainly wouldn't relate the lung cancer death to PVC unless you knew, for instance, the smoking habits of the individuals that you are studying.

DR. PETERS: Well, one would have to -- to -- to --

MR. CONNOLLY: What significance is the fact that B. F. Goodrich had ten suicides in comparison to expected 5.3 suicides?

DR. PETERS: I do not know.

MR. CONNOLLY: Let me see if I understand what you are saying.

You started off by indicating that the Tabershaw-Cooper study overlapped your study, is that correct?

DR. PETERS: Most of our employees were in their study, yes.

MR. CONNOLLY: So, wouldn't it be safe to say that the Tabershaw-Cooper study is probably more statistically significant than your study?

DR. PETERS: It's bigger.

MR. CONNOLLY: Is it more statistically significant?

DR. PETERS: The use of that term in this context is meaningless to me.

MR. CONNOLLY: I am having a great deal of difficulty understanding you.

You say that the deaths in four B. F. Goodrich plants are not statistically significant?

DR. PETERS: I didn't say that. I said the samples were small and we chose not to use them.

MR. CONNOLLY: I thought you said they were not statistically significant.

DR. PETERS: I have been trying not to use those terms, because I don't know what they mean.

MR. CONNOLLY: Are they relevant?

DR. PETERS: I think they -- the particular studies that I presented I believe are relevant. We did not consider the other smaller plants, smaller number of deaths relevant.

MR. CONNOLLY: Is the Taberslane-Cooper study more relevant than your study in that it encompasses a greater variety of plants throughout the country?

DR. PETERS: I think that it is certainly more representative, and you might want to argue about what relevant means, but it is interesting to note that they found excess of brain cancer as well.

MR. CONNOLLY: Did they also find that it was insignificant, the numbers were insignificant to make a valid determination?

DR. PETERS: Well, one could argue about the statistics that they used. I would rather not get into that now.

MR. CONNOLLY: I don't blame you.

Let me ask you this question: I am asking this, not knowing the answer, as a neophyte. If you did a epidemiological study on a plant and you found, for instance, that 95 percent of the causes of all deaths in the plants were less than what was expected in the over-all white male population, could you draw any significance from that?

DR. PETERS: I am not sure that I understand the question.

MR. CONNOLLY: Well, let us assume, for instance, in analyzing the causes of deaths, of any given facility, you find perhaps twenty different causes of death.

DR. PETERS: You would by chance expect to find one at the .05 level, if that is the question.

MR. CONNOLLY: No, that isn't my question.

My question, assume you found that 95 percent of the causes of death were less than was expected, could you draw any conclusions from that?

For instance, if the plant's [illegible] with the rest of the population, white male population --

DR. PETERS: Well, there are some [illegible] factors which produce working populations. I don't think I would be willing to make that judgment because if there is medical screening involved, that leads towards healthier people working. If you are sick, obviously you don't go to work, so there is all kinds of things that make the working population look healthier and actually be healthier.

MR. CONNOLLY: Isn't it true that liver cancer can be caused by hepatitis?

DR. PETERS: I don't know that that is the case.

MR. CONNOLLY: Is it possible?

DR. PETERS: I think it is possible.

MR. CONNOLLY: I don't have any further questions.

JUDGE MANT: Yes, sir?

MR. SEBASTIANELLI: My name is Sebastianelli from Air Products.

You said that you took the statistics from the vinyl chloride monomer plant of Goodrich and one PVC plant of Goodrich?

DR. PETERS: The one plant -- oh, was a polyvinyl polymerization plant.

MR. SEBASTIANELLI: And the other one?

DR. PETERS: Well let's see. Let me go back.

One poly -- or vinyl chloride monomer is produced in the other one.

MR. SEBASTIANELLI: And what were the statistics from the vinyl chloride monomer plant in terms of how many died in that one plant?

DR. PETERS: I can't give you the breakdown.

MR. SEBASTIANELLI: There is no breakdown?

DR. PETERS: There is a breakdown, but I can't give it to you today.

MR. SEBASTIANELLI: Was it one, do you know, from the vinyl chloride monomer plant?

DR. PETERS: One what?

MR. SEBASTIANELLI: One angiosarcoma from the vinyl chloride monomer plant?

DR. PETERS: I do not know that. I think Dr. Monson knows that, but he is not here.

MR. SEBASTIANELLI: You have made a recommendation for the polyvinyl chloride industry and for the vinyl chloride monomer industry, isn't that correct, in your last statement?

DR. PETERS: The one -- both plants, workers were exposed to vinyl chloride.

MR. SEBASTIANELLI: Is your recommendation to these plants or to the industry? Thirty-seven plants, and you only looked at one.

DR. PETERS: My recommendation as a physician interested in preventive medicine is that I would not want workers exposed to vinyl chloride. I support the standard as proposed.

MR. SEBASTIANELLI: Do you know the differences in operation between the 37 plants?

DR. PETERS: No.

MR. SEBASTIANELLI: You only looked at one plant, and your recommendation is for 37?

DR. PETERS: You can say that.

MR. SEBASTIANELLI: Is it usual for you to make a recommendation for an entire industry that composes more than 37 plants on the basis of a review of two?

DR. PETERS: Well, that is the way it usually happens

because not all plants get studied like this.

MR. SEBASTIANELLI: In other words, when you make a recommendation on the basis of a medical survey that affects many plants, you do it on the basis of the two plants that have the most horrendous statistics on the disease?

DR. PETERS: I think you go by what health information you have available.

MR. SEBASTIANELLI: Did you not have health information available from the other plants?

DR. PETERS: No, we didn't.

MR. SEBASTIANELLI: You did not ask Air Products for the death certificates of its plants?

DR. PETERS: No, we didn't.

MR. SEBASTIANELLI: You did not. But you make a recommendation--

DR. PETERS: I'll tell you one thing we did do, and that was that we applied for the MCA proposal to do the epidemiological study a year and a half ago that went to Tabershaw-Cooper.

MR. SEBASTIANELLI: I see. Thank you.

JUDGE MYATT: Any other questions? Mr. Samuels.

MR. SEVERSON: Doctor, of the workers who have already been exposed to high levels or any levels over a long or short period of time, would you recommend any further exposure?

JUDGE MYATT: All right, Mr. Fleming?

MR. FLEMING: Thank you, Judge Myatt.

I am Richard Fleming, Group Vice President of Air Products and Chemicals, Incorporated. I am responsible for the chemical group of our company, headquartered at Valley Forge, Pennsylvania.

Testifying with me today are Mr. John G. Barr, Technical Manager, Manufacturing, on my right, and Doctor Paul Kotin, M.D., our consultant on vinyl chloride monomer medical matters.

Also here with me today are Doctor A. Ross Adams, General Manager, Plastics Division, Mr. T. L. Carey, Vice President of Manufacturing, and Mr. Joseph Sebastianelli, attorney.

Air Products operates two plants for the production of polyvinyl chloride, based on the suspension process, located at Pace, Florida and Calvert City, Kentucky. Combined capacity of the two plants is approximately 200 million pounds per year, or approximately 3.5 percent of the total PVC industry.

Air Products also operates a PVC compounding facility at Calvert City, and a small plastic fabrications plant at Morristown, New Jersey, Costa Mesa, California, Durant, Mississippi, and Homestead, Pennsylvania.

In addition, we now operate a plant at Calvert City

for the production of a different class of polymers sold as water emulsions, which also use vinyl chloride as one of several monomers for a portion of its output. And we have a second plant of this type now under construction at South Brunswick, New Jersey.

The total number of employees engaged in all of these operations, including service, support and management, is about 500.

Air Products is a non-integrated producer of PVC; we purchase all of our own materials, and are only very slightly integrated forward into fabrication, using less than two percent of our PVC production.

We are about tenth in capacity among PVC producers, and a relatively large proportion of our output is in special types of polymers. Our PVC plants have been operating since 1957 and 1959, each coming to Air Products as part of acquisitions of larger business -- the Florida plant in 1969, the Kentucky plant in 1971.

Air Products has participated in industry studies of health hazards of VCM and will continue to do so. Our own medical examination program, which will be discussed later by Doctor Kotin, has covered approximately 480 present employees.

We have also studied the mortality experience of all employees who have worked in these plants since their

inception; we have found no cases of angiosarcoma.

Air Products and Chemicals is deeply concerned about the question of appropriate protection of the health of its employees and of all of those involved in the VCM-PVC industry. We are participating fully in whatever activities we can recognize as worthwhile in developing facts that permit determination as to what that health protection means in practical terms.

We believe in establishing and observing soundly conceived regulations designed to assure safe working conditions; we are also very concerned that unwisely conceived and unnecessarily restrictive regulations not be promulgated. Such regulations work to the disadvantage of all concerned -- worker, company, consumer and the economy as a whole.

Thus, our purposes here today are as follows:

A. To present for the public record a resume of our study of the health of our own employee population and to offer the conclusions our medical consultants have reached from these studies at the present time. This is meant as a contribution to the national study of employee health in the VCM-PVC industry that is so urgently needed to guide the formulation of safe practices.

B. To offer some perspectives on what we consider some key issues relative to arriving at appropriate regulations.

C. To provide testimony on what we believe is feasible and workable, and why, in the way of a regulated occupational exposure to viny chloride.

D. To dfer some detailed comments on the proposed regulation for the consideration of those who will write the final one. These will not be presented orally at this meating, in the interests of time, but will be a part of our written summation.

In much of the information presented prior to and during these hearings, it has been and probably will continue to be stated, by many observers that general concern about human exposure to vinyl chloride has passed through three distinct phases, as follows:

Phase 1, a period in which fire and explosion concerns and concerns about narcotic effects seemed most important.

Phase 2, concerns regarding AOL.

Phase 3, concerns regarding carcinogenicity.

Phase 1 concerns were the only ones of significance from the inception of manufacture and polymerization of vinyl chloride in Germany in the early 1930's until the early 1960's -- a period of 25 to 30 years.

During this period, VCM was used as an anesthetic, such was the understanding of its toxicology during this time. A number of toxicological studies made during this period

show only minor effects from exposures to what were usually high dosages for relatively short periods of time, compared to the more recently published information concerning longer-term exposures.

AOL was first observed in PVC workers in 1962, both here and abroad, and in about 1966, a causal relation between VCM exposure and AOL was established. Since AOL was almost exclusively among reactor cleaners who came into frequent physical contact with VCM, precautions were taken to limit or eliminate this, and the incidence of AOL declined, markedly.

These and other plant and operational changes resulted in lower exposures of operating personnel generally to VCM concentrations.

Industry-conducted toxicological studies, exemplified by those extensively reported by DOW, showed that lower exposure levels were necessary to avoid the possibility of the toxicological effects of chronic exposure. Specific standards of 500 parts per million TWA, and then a 500 part per million ceiling, were set by ACGIH and then later by OSHA, and these were met by industry.

The actual levels of VCM in plant atmospheres to which workers were actually exposed is not a matter of record. The need for such information was not understood, and the instrumentation to readily measure it was not available for most of the period of historical operation.

Attempts now to reconstruct historical exposure levels are admittedly crude, but they are nonetheless instructive. The lower exposure limits for VCM in air at ambient conditions is 3.6 percent; that is, 36,000 parts per million. In the Phase 1 period, this was the absolute upper limit of concern to plant operators; even with a safety factor of 10, levels of 3,600 parts per million would have been tolerated if no other problems were found or expected.

It is reasonable to expect that such levels were encountered at times of early operations by some individuals. It is very difficult to reconstruct a pattern of frequency of early peak levels of exposure in any reliable way; it has been more realistic, and perhaps more pertinent, to attempt estimates of the average long-term continuing exposure to which an individual was subjected.

Thus, TWA data have been used to characterize the cumulative long-term dosage thought to have been experienced by workers in PVC plants.

The Chemical Industry Association of the United Kingdom has recently stated their estimates of the average TWA exposure of workers in United Kingdom plants. These estimates show the following variations over time:

1945 to 1955; an average TWA of 1,000 parts per million.

From 1955 to 1960, 400 to 500 parts per million.

From 1960 to 1970, 300 to 400 parts per million.

In mid-1973, 150 parts per million.

And currently, 50 parts per million.

Since the technology and equipment used in the English operations, and economic and safety considerations concerning VCM loss control were not appreciably different from those prevailing in the U.S. or other parts of the world, for that matter, one could reasonably expect similar estimates to characterize operations in this country.

In fact, it is our judgment that these figures are reasonable estimates of what prevailed, on average, in this country. Our current estimates for our own plants are about the same as this table.

Note that these are average figures, so that some plants must have been higher at least part of the time. Furthermore, it seems clear that within those plants, some individuals probably had even higher exposures.

The recent liver cancer findings are the legacy of this type of exposure. Each case found to date has involved an individual who has worked through periods of high-level exposure by any current date measure, and all have worked for some time in jobs where the highest individual exposures have been encountered.

Thus far, the extensive search of the human experience for angiosarcoma among workers in VCM-PVC plants has

turned up 19 cases since 1961. Of these, 13 are in the U.S., found among the employees of 15 VCM plants and 36 PCV plants.

Of the thirteen cases, seven have occurred at one PVC plant and three at another. A U.S. total of four such PVC plants have had no cases.

There are thus 47 plant worker populations who have no record of angiosarcoma, although they have lived through periods of exposure well above levels no one would tolerate in the light of current information.

There is a considerable body of animal exposure data to show decreased hazard with decreasing exposure levels to VCM. Moreover, the human experience in its plants reported by DOW at the February hearing held by the Department of Labor has shown no incidence of angiosarcoma among its workers from long-term average exposures of between 100 and 200 parts per million, TWA.

Air Products' own health studies show one case of AOL, and no other health problems relating to exposure in our operations to date.

Although exposure levels in fabricating plants have generally been very low, exposures in a few jobs in these plants have historically probably been on the order of 15 to 25 TWA. Until the recent announcement of the GE wire-coating case and the case of the accountant at a vinyl sheet-producing plant, there were no reported angiosarcoma cases among fabri-

cation plant employees.

As we have heard in testimony at this meeting, any relationship between these cases and exposure to VCM remains conjectural at this time. Careful study of the very large body of human experience already available in the history of PVC fabrication operations is clearly warranted and can shed important light on the hazards of relatively low-level experience.

Exposure levels in VCM plants are generally considerably lower than in PVC plants, because of the continuous process technology of the monomer operations and the generally outdoor construction of these plants.

Only one angiosarcoma case has been found among VCM workers in this country, and this man is reported to have worked on very high-exposure tasks relating to sampling and catalyst tube cleaning. He also worked in PVC for the final year of his working life.

All of these considerations lead to the idea of a relatively safe but readily measurable level of VCM in a work environment.

We therefore support the proposal for a 25 TWA exposure level to become effective October 5, 1974, that was part of the SPI recommendation. As we will show later, we believe that this level is also feasibly attainable, though a difficult and expensive one to continuously meet 100 percent

of the time, as we would hope to do under such a regulation.

Lower levels proposed for later achievement by SBI are much more difficult and much more speculative as to achievement at this time, in our view. This, too, will be elaborated on by Mr. Barr.

Any level of exposure that is required by the new standard that is below current achievement confronts a producer with essentially three alternatives.

One; since he does not meet the standard, he can shut down and abandon the business. The economic consequences of this on the producer and his specific employees are apparent. The effect on his customers depends upon what alternative sources of material they can find. SBI testimony and extensive questioning has covered this in some detail.

Two; the producer may make changes involving capital expenditure or otherwise to bring his operation into compliance. Depending on the severity of the standard, this will take more and more fundamental and expensive changes, and thus longer and longer times, and may reduce output, although not stop it entirely.

Or, three: he may decide to replace his current plant with a new one designed to meet the new standard. This route, of course, requires the most in time and capital money.

Thus far, all producers have been proceeding according to alternative Two. Everyone has obviously done the

quickest, easiest, most effective things first. This has permitted most of us to quickly approach conformance to the emergency standard now in effect. I say "approach," because I do not believe that any PVC producer is able to stay below 50 parts per million 100 percent of the time at every location in his plant currently.

I know that we are not, in spite of our most strenuous efforts, and I believe we may be ahead of a number of other producers in measures we have taken.

Because of the volatility of VCM and the internal pressures in PVC equipment, every flange, valve, pump, compressor, heat-exchanger and other piece of process equipment is a potential source of leaks. Much of the equipment must be opened routinely for cleaning and inspection to insure safe operation, and large quantities of air pass through other items of equipment, such as centrifuges and driers. There is no one thing that can be done to limit VCM loss to the plant atmosphere; there are literally hundreds of leaks or potential leaks to deal with.

This should make it clear how hazardous are estimates of future achievable VCM levels in plant air, and how likely it is that excursions in these levels will unpredictably occur from time to time. Replacement of older equipment with newer types, which are designed with minimum leakage in mind, depends upon the availability and deliverability of such replacements. Delivery of even an exhaust fan takes

months in the current high capital spending environment. Major equipment takes many more months.

Although we are at Air Products not at all satisfied with our ability to guarantee conformance with the current emergency standard, we support the 25 TWA proposal for October 5th, 1974. We need the delivery of new equipment to meet this level, but we have some confidence that we can meet it.

The concept of a ceiling level, and how it is to be measured and administered, requires clarification in the proposed standard, and Mr. Barr will cover this in more detailed comments to follow.

Alternative 3 requires some comment.

For any producer of PVC other than one who also produces vinyl chloride monomer, this alternative is not currently a realistic one. Air Products, for some time, has been attempting to develop an assured source of supply for enough monomers to build a new, modern PVC plant. We are naturally reluctant to do this without such a source. Two years of contact and/or negotiation with every conceivable supplier have yielded nothing of substance.

We can foresee no change in this situation for some time. At least until substantial new monomer capacity is announced for merchant sales and is nearing production. No such plant, which takes three years to build, is now in

prospect. Under these circumstances, should any significant part of the industry be forced to shut down by unrealistic regulations, greatly increased concentration of the industry will result.

Any estimate of achievable levels in the plant atmosphere is, of course, dependent on the degree of plant ventilation permissible as well as on the degree to which VCM is released. Virtually all of the testimony presented in this hearing has been, and probably will be, based on the basic presumption that very extensive use of ventilation is an acceptable practice. This is so because no practical technology exists for the removal of VCM from large volumes of plant air. It seems clear from current information that this presents no real problems, but it must be recognized that unrealistic actions in the way of external environmental regulations can negate practicality just as easily as unsound in-plant regulations.

Consideration of fabricating operations as potentially regulated ones must also be given. There are sufficient data now becoming available to warrant a judgment that if resins containing not more than .05 percent by weight of uncombined monomer are shipped from the polymer plants, that there is no need to regulate warehouses, shipping facilities or fabrication operations. Data to support this will be offered by Mr. Barr.

There are two possible places in fabrication operations that should have some precautions in effect, however. Such precautions seem to be already adequately covered by existing OSHA requirements.

At the point where the PVC container is first opened, the contained air, although quite small in volume and in absolute VCM content, may be high in VCM concentration. In an impervious container, such as a tank car or silo, the concentration will usually be somewhat above the corresponding parts per million of free monomer in the resin. In a porous container, like a paper bag, the concentration in the contained air will be very noticeably lowered. In either case this air should be exhausted outside the work area by appropriate ventilation means.

In a similar way, gases evolving from the first heating and exposure of the molten resin should essentially be similarly vented.

With these simple precautions, the atmosphere in the fabricating work space may be expected to be at levels not exceeding two parts per million, and probably very much lower. TWA's for such plants might be expected to average one or less for the employees involved.

I would point out that these estimates presented here were given before we were aware of the data you received earlier today from these fabricating people.

We therefore recommend that fabrication facilities processing resins of less than .05 percent in uncombined VCM be considered non-regulated areas within the meaning of the proposed standard.

I would now like to turn the discussion over to Mr. Barr.

MR. BARR: Good afternoon, Judge Myatt.

My name is John G. Barr.

These comments are presented for your consideration and are based on the best information available to us now. I shall discuss first the sources of exposure to our workers and the methods of exposure reduction which we have used.

Second the methods of monitoring.

Third, the programs for exposure reduction which we have in progress.

Four, the situation in fabrication plants which we have studied.

Five, a summary of our specific comments on the proposed standard.

In addition, we will submit a detailed written commentary on the standard with suggested changes.

About 80 percent of the PVC which is manufactured in the United States today is made by the process which APCI employs -- that is, the batch suspension process, and most plants -- as do ours -- contain a multiplicity of relatively

small reactors. These reactors must be opened frequently for charging and cleaning. It is the vapors from these operations and from the VCM degassing from the slurry and dry powder that form the greatest sources of monomer exposure to workers.

The second greatest source is the fugitive emissions from leaks at gaskets, valves and valve stems, pump seals and other mechanical joints in the piping of the plants. These two sources will continue to be a problem, no matter how well maintained or how carefully operated is the plant.

Monitoring of the VCM concentrations taken in our plants during the last week in January of this year disclosed that we had many areas around reactor, pumps and weigh tanks that contained concentrations in the 200 to 400 PPM -range, with a few isolated points even higher, although the general work space was generally in the 50 to 200 PPM range. This survey substantiates the results of earlier tests.

At this time, APCI accelerated its monomer exposure reduction program, which had been started almost a year earlier. We mounted a major engineering and renovation program, including extensive revising of operating procedures, to reduce the chance of release of monomers inside the building, special retraining of operators, and augmentation of the total ventilation system for buildings and equipment. We instituted the use of airline respirators for reactor cleaning or entering

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vessels containing monomers, and while doing maintenance work that could release monomers.

We were fortunate that we had placed on order, in the summer of 1973, much of the equipment needed for the polymer building ventilation improvements, and that this was in fact being delivered in early 1974. Other equipment was obtained from wherever available; some was diverted from its intended application in other areas for this purpose.

Immediate attention was given to the trouble spots by the assignment of all available technical and maintenance personnel. This allowed us to reduce exposure to the point that by the time the temporary standard of 50 PPM took effect on 5 April 1974, we were already in substantial compliance.

Continued work has enabled us to achieve an average eight-hour TWA in the 20 to 25 PPM range for our workers in the polymerization building, and even lower for those in some other job locations. Once again, it must be pointed out that these are average TWA figures, and that many of our results are above this average.

Moreover, we are still having difficulty in obtaining -- maintaining our workspaces below the present standard of 50 PPM ceiling all the time, since it is impossible to guarantee that a leak will not develop and that an employee will not be exposed temporarily to a concentration above the specified level, no matter what that level may be.

We want to emphasize the difficulty of a ceiling concept. Technology does not now exist that will give instantaneous readings of monomer concentrations at the worker breathing zone. Therefore, there must be an allowable time period in the standard for the monitoring system to sense a rise in concentration and to warn the employees to put on breathing protection.

In addition, the use of that breathing protection must be permitted on a continuing basis when a designated ceiling is exceeded. We can not understand the validity or practicality of the ceiling standard without such provisions, since it is not reasonable or enforceable, and in the last analysis we believe that the best basis for the protection of a worker is the control of his total exposure.

Another point which needs emphasis is that while stopping VCM emissions at their source is clearly the first exposure control priority, the ability to continue to utilize ventilation is essential to overcome the effects of inevitable leaks and losses from any practical system.

As to our monitoring methods and efforts, we have found that two basic monitoring programs are necessary in order for us to understand completely the problems which we must solve; first, area monitoring, and secondly, determination of individual employee exposure by personal monitoring.

Area monitoring was first performed in our plants

with a portable total hydrocarbon analyzer, which is still being used regularly as a leak detector, and to cover those areas which are not covered by the fixed point monitors.

We were able to have a ten-point fixed monitoring service in each plant by early April. This is a chromatographic device which separates and measures the actual monomer concentrations. A second ten-point instrument is now in service, giving us 20 points at the present time for our area monitoring in each plant.

Personal monitoring has been in effect since late February, using the carbon cube method, and we now have four months' experience. We have found that eight-hour measurements are more reliable and give more realistic data than do the shorter sampling periods which have been recommended.

All three of these instruments have been cross-checked and calibrated against our laboratory chromatographs, first by using identical samples on all instruments simultaneously, and secondly, by taking field samples and rerunning them in the laboratory. We have found the correlations to be excellent, and therefore recommend that both methods be employed.

Programs in progress; we have completed nearly all of those things which can be done with materials and technology at hand. Further improvements require substantial outlays of engineering effort, capital, and above all, time to obtain

and install the necessary equipment

We have had on order for almost five months now rotating vane compressors to replace the reciprocating machines currently in service in our monomer recovery section. These existing compressors are a source of monomer because of leaks at the shaft seals; the presently promised delivery indicates that we will have the new compressors in service by July of 1975.

We have been working for more than two years and have spent more than a million dollars on the development of a solvent cleaning system for the polymerization vessels. This would effectively eliminate the need to open or enter the vessels, and thus greatly reduce exposure potential. We are not yet completely satisfied with the system, and the recent request for quotations on the required equipment to expand the system from its present level of operation resulted in estimated delivery times of from two to two and a half years, after the order is accepted.

Even standard equipment such as pumps and valves run several months to a year for delivery, and as all of the industry knows, it is impossible to get early delivery on monitoring equipment, apparently because of large orders placed by Governmental agencies.

Other quoted delivery times for the types of equipment which we will need are:

pressure vessels, such as reactors or strippers: two years or more;

instruments: 12 to 14 months;

field-erected tanks: 16 to 20 months;

structural steel: 10-16 months;

centrifuges: 20 months to 2 years.

This situation will deteriorate rather than improve as more companies move to reduce their exposure, and we can expect that at least two years will be necessary for any major capital improvements.

Even assuming, however, that major improvements are committed to, we can not expect to accomplish any further order of magnitude improvements such as we have achieved in the past six months. The very fact that our worker exposure is now averaging 20 to 25 TWA is in itself indication that many of the readings are above 25, with a few above 50, and we expect that we shall have a very difficult time maintaining all eight-hour TWA exposures at a level below 25 PPM, if in fact we can do it at all.

We can support the SPI proposal of 25 TWA as a goal that we have a reasonable hope of achieving by October 1974. Beyond that, we can not state with certainty the results of technology which is yet to be applied.

We believe that PVC fabrication operations do not require regulation under standards being considered for

monitoring polymer plants, since exposures to monomers at the fabricating plants which we have studied are now very low, because very little monomer is present in these plants.

The monomer content of our resins follows a pattern very similar to that of the monomers in the workplace. Levels of one-tenth to two-tenths percent by weight in the resin were quite normal as recently as 1973. The steps which were taken to reduce worker exposure in the polymer manufacturing plants have produced as a side effect a reduction of the residual monomer.

In addition, other work programs have been aimed specifically at this problem, because at present we can manufacture most -- but not all -- resins containing less than one-tenth percent of free VCM.

Air Products has a line of specialty resins, that represents a small portion of its output, with quite low residual levels. The majority of the general-purpose resins, however, representing 65 to 75 percent of all our production, now fall into the range of .25 to .75 percent by weight. We believe that with present programs we can achieve by October, 1975, a goal of .05 percent for all resins at the time of shipment from the plant, and of course, the actual content by the time it is processed will be lower than this.

Our position was substantiated by the results of measurements of the monomer levels in a number of our customers'

plants as well as in our own compounding and fabrication operations. We have found these exposures to run no higher than one to two PPM, and they generally will run well below .05 PPM. These results are being obtained while processing polymer of the normal monomer content, and with the standard ventilation of the type which is required for ordinary industrial hygienic purposes.

A further important point is that there is no potential for large releases of monomer at a fabrication plant, as there could be at a monomer or polymer operation.

Neither do we see any problem in the transportation of polymer. For example, should a 40,000 pound truckload of PVC containing .05 percent by weight VCM lose even a half of its VCM over a several-day trip, this would only amount to a loss of ten pounds of monomers, which would be so diluted along the route that it would be unmeasurable.

Thus, we can recommend without reservation the exemption from the standard of facilities involved in the handling of materials containing less than .05 percent by weight uncombined monomers.

We have prepared a detailed list of objections to the proposed standard as published, and have supplied alternate wording where it is needed. Some of thees suggestions differ substantially from other proposals which are being made, and we urge your serious consideration of them. In the

interests of brevity, we are submitting these in writing as Appendix A, and ask that they be made a part of the record of this hearing. A very brief summary will be given here.

First we propose to substitute a limit of 25 TWA, 40 ceiling, in place of the no-detectable level.

Monitoring should include both the work zone and the employee.

Respirators may be of the half-face or full-face air-supplied type, and shall be worn as soon as possible after it has been detected that the ceiling has been exceeded.

Impervious suits should not be required, but clean work clothing be furnished as appropriate.

We propose that the permanent standard not apply to PVC, waste streams or finished or semi-finished product, including compound, which contains less than .05 percent by weight of uncombined vinyl chloride, or to the transportation or processing of PVC with this level of free VCM.

In conclusion, we respectfully submit that the proposed permanent standard fails to meet the basic requirements in the Occupational Safety and Health Act of 1970, either as to necessity or as to technical and economic feasibility, and that it represents a substantial departure in principle from other standards promulgated by OSHA. Many of its specific requirements are either impossible to meet or unnecessarily restrictive, and some offer greater hazards than that which

they propose to remedy.

We therefore request your serious consideration of our comments and suggested changes.

MR. FLEMING: Now, Doctor?

DOCTOR KOTIN: My name is Paul Kotin. I am a physician, graduated from University of Illinois Medical School, and my specialty is pathology; I have been a practicing pathologist and experimental pathologist during all of my career, a career which began with World War II, following which I entered the private practice of medicine in pathology for two years, went to the University of Southern California where I was, for fifteen years, leaving as the Paul Professor of Pathology.

I entered Government service in 1961 as the Scientific Director for Etiology at -the National Cancer Institute; five years later served as the Founding Director of the National Institute of Environmental Health Sciences.

I was with Government until 1971, when I left to go to Temple University as Dean of the Medical School and Vice President for Health Sciences, and since June 1st of this year I have been Vice President for Health, Safety and Environment of the Johns-Manville Corporation.

My entire research career has been devoted to environmental diseases, especially environmental carcinogenesis,

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and when not with the Government I worked both sides of the street; I was a consultant for a variety of Federal agencies as well as a consultant to private industry.

What I would like to do now is give you a report of the results of the screening of the present employees of Air Products and Chemicals Incorporated, who are engaged in the handling of vinyl chloride, and on the results of an examination of death certificates of those VCM employees who left the company or died while employed.

I was employed as a consultant by Mr. Richard Fleming, Group Vice President, Chemical Group of Air Products and Chemicals, in early February 1974, for the specific purpose of establishing and conducting a medical evaluation and surveillance program for employees exposed to vinyl chloride.

MR. KLEIN: Excuse me, Your Honor. If I could interrupt, our copies don't have the good Doctor's presentation.

Would you have any extra copies, Doctor?

DOCTOR KOTIN: No. Actually, I don't because it was rewritten as of last night, incorporating the most recent data from our studies of employees and data from laboratory tests. It will be submitted for the record.

JUDGE MYATT: All right, Doctor; proceed.

DOCTOR KOTIN: As a first step, two physicians were identified in the areas where Air Products has vinyl

chloride operations -- Doctor William M. Blaylock, of Paducah, Kentucky, and Doctor Bartley Beitelman, of Pensacola, Florida agreed to serve, and in consultation with them, a medical examination protocol was developed and carried out for employees in plants at Calvert City, Kentucky, under the supervision of Doctor Blaylock, and at Pace, Florida under the supervision of Doctor Beitelman.

Both physicians are certified by the American Board of Internal Medicine. Doctor Blaylock is a specialist in gastroenterology and hepatology, and Doctor Beitelman is a member of a large medical group with specialists in gastroenterology and hepatology.

Following several meetings between myself and the two physicians, a screening and review procedure was adopted for Air Products' employees at the two plants. Special emphasis was directed toward identifying and specifically testing for the two diseases for which there were demonstrated associations between vinyl chloride exposure and disease -- acroosteolysis and angiosarcoma of the liver.

These areas of emphasis were just part of the complete review of each patient, which included the following:

A complete and detailed medical history was taken on each employee. Afterward, a physical examination and a series of laboratory procedures were performed, as follows:

Chest X-ray.

Hand X-ray.

A battery of laboratory tests which I will name, for the purpose of making a point in a few moments.

Blood urea nitrogen.

Uric acid.

Phosphorous.

Calcium.

Alkaline phosphatase.

Total protein.

Albumin.

Bilirubin.

Cholesterol.

Globulin.

Glucose.

Serum glutamic acid transaminase SGOT.

Lactic acid.

Dehydrogenase.

LDH.

Alphafeta protein.

Carcinoembryonic antigen.

Complete blood count with platelets.

And serum glutamate pyrubic transaminase SGPT.

I list this battery of tests, over half of which are specifically directed to the liver, to indicate that it is a battery that is required to evaluate liver function. No one --

not even this group of tests -- is fully informative at all times.

Minor differences in the laboratory tests performed in Florida and Kentucky reflected the availability of laboratory resources.

Testing showing abnormal laboratory findings in any employee were repeated to assure their authenticity. In addition to the repetition of the preceding tests, when indicated, the following additional tests were performed on employees not previously having these tests: the two important ones were liver-scans and liver biopsies.

The persistence of abnormal laboratory findings, or the presence of signs and symptoms suggesting liver toxicity was followed by a further re-examination of the employee for the specific purpose of determining the desirability of a liver-scan and possible liver biopsy.

At Pace, Florida, 201 employees were tested, and 13 employees were found to have test results which varied from established norms. All these 13 employees were retested; four employees had normal results on retest, three employees had persistent minor variations which, in our opinion, did not require further testing at this time. These employees are scheduled for retesting in 90 days to determine their persistence.

Liver-scans were performed on six of the 13, all of which were normal. One case of acroosteolysis was found

during the examination, and this employee has been removed from vinyl chloride operations.

At Calvert City, Kentucky, 291 employees were tested. On the infial tests, we found 97 employees who had findings which varied from recognized norms. Equipment malfunction was suspected, and verified, and upon retest, 29 employees showed persistent abnormalities.

These 29 were scheduled for immediate retest. 16 employees showed persistent equivocal variations; as in the case of Pace, Florida, they are scheduled for retest within 90 days.

Of the 13 employees with persistent abnormalities when retested, six showed findings which directed to more complex and increasingly sensitive and diagnostic tests for liver physiology and anatomic state.

The six employees were examined by liver biopsy, intravenous pyelogram, upper and lower gastrointestinal series, a gallbladder X-ray, a repeat of the chest X-ray, and a complete physical re-examination.

Of the six biopsies, two were diagnosed as cases of Gilbert's disease, a congenital abnormality of enzyme metabolism, one case was identified as having chronic gallbladder disease with an anatomically abnormal gallbladder -- an intrahepatic gallbladder, a gallbladder buried within the liver, and this is what gave us the cold spot on the liver-scan.

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One case was diagnosed as having chronic gallbladder disease with coexisting persistent hepatitis.

One case showed chronic persistent hepatitis subsequent to an infectious hepatitis, and one case showed no abnormality.

I also examined the death certificates of former employees who had been engaged in the manufacture of vinyl chloride and who died either while working for or subsequent to leaving the company. I was unable to identify any relationship between the causes of death and the exposure to polyvinyl chloride in their work environment.

Throughout the entire testing and examination programs at both Air Products plants there were constant discussions between the physicians on site and myself; often on a daily basis. In addition, I have been to both the plants in Florida and Kentucky and personally reviewed records with the local physician.

I would conclude at this time that except for the case of acroosteolysis discovered in an employee in the Florida plant, the results of the screening comprising medical and environmental history, X-ray, physical examination, laboratory tests -- and where indicated, liver-scan and biopsies -- findings or diagnosis which point to VCM as a positive agent or mechanism were not identified.

More specifically, we can state at this time that

no cases of angiosarcoma have been identified.

JUDGE MYATT: Before you start, Mr. Fleming, you have submitted your statement and Mr. Barr's, and an appendix with it which is attached to it?

MR. FLEMING: Yes, sir.

JUDGE MYATT: All right, Mister Reporter, for the record, the statement of Air Products will be Exhibit 23-A and the Appendix will be 23-B, and I will ask you to designate in the record, although you do not have a copy, the report of Doctor Kotin as 23-C, and he is to supply us with a copy of that as quickly as possible.

(The documents referred to were marked for identification as Exhibits 23-A, 23-B and 23-C, inclusive.)

JUDGE MYATT: Mr. Klein, proceed.

MR. KLEIN: Before beginning with the actual questioning, I would ask that, if you would, you provide in the post-hearing comment, the various job classifications in your various plants, the approximate exposure of persons in those job classifications -- that is, what sources do they come near, and whether -- indicate if you could whether it is an intermittent type exposure or a continuing exposure.

MR. FLEMING: We will of course provide whatever

data you feel is helpful, but I would be interested in understanding why this data is helpful just as a matter of interest.

MR. KLEIN: Well, I really don't want to take the time now to go into a detailed explanation here.

MR. FLEMING: There isn't a two-sentence explanation?

MR. KLEIN: Well, I think it certainly would indicate -- the job classifications that have the most exposures and the job classifications that have the least exposure would also indicate how long the exposure might be, and also would have some relevance with respect to respirators, I believe.

MR. FLEMING: We most certainly will supply that.

MR. KLEIN: We would appreciate that.

With respect to the recommendation, that you apparently agree with, that SPI made, is it the basis of your conclusion that those should be the standards the same as SPI's basis? That is, sort of a judgment callon the part of people in the industry?

MR. FLEMING: Well, I think it is abundantly clear from all that has been said that there most certainly has to be judgment, and yes, sir, it is a judgment call.

MR. KLEIN: And do you have any other additional bases, other than the ones that have been indicated in the prior testimony?

MR. FLEMING: No, I think we are looking at the same

basic array of information.

MR. KLEIN: I take it you have been monitoring considerably at present?

MR. FLEMING: Yes, that is so.

MR. KLEIN: And for approximately how long have you been monitoring your operations?

MR. FLEMING: I think Mr. Barr indicated about four months with personnel monitoring, and with fixed-point monitoring for a somewhat shorter period, but I think he gives that information in his testimony.

MR. KLEIN: On page ten of the testimony, you indicated that equipment must be routinely cleaned, and inspected. Can you give us a range of what you mean by routinely cleaned?

MR. FLEMING: Well, I can give you some information, yes. For example, other people have commented about their frequency of reactor cleaning for you; we, of course, like the rest of the ilustry, must do reactor cleaning. In those reactors where we do not use solvent cleaning, we are entering those reactors to clean them somewhere in the range of four to eight batches -- each four to eight batches.

In those where we are using solvent cleaning, we go in very much less frequently, on the order of once every 25 to 40 batches, and generally speaking, the principal reason for entry is maintenance problems rather than a cleaning one.

MR. KLEIN: Is there a technical reason why solvent

cleaning can not be used on certain types of reactors?

MR. FLEMING: Well, as in our case, as we indicated in our testimony, we have been working on the development of a solvent-cleaning technique for quite some time, and we are not satisfied with that system.

We have some significant difficulty with it, primarily in relation to recovery of solvent for re-use, separating it from the dissolved polymer, and it is in these areas that we are trying now to improve that technique.

Furthermore, the system that we have currently is not capable of treating all our reactors.

MR. KLEIN: Is there anything inherent in the reactor itself that will prevent solvent cleaning?

MR. FLEMING: Well, we are applying solvent cleaning on stainless steel reactors and on new glass-lined equipment; there is a problem in the older glass-lined equipment where the base metal behind the glass lining is not stainless steel, and there is a problem there.

The solvent cleaning cleans those holidays in the glass lining so well that you get very large accumulations of polymers sticking to the walls at that point. It is not a workable situation.

MR. KLEIN: I think you indicated that you have had some fairly recent, fairly dramatic reductions in the exposure levels. Could you indicate to us any work practices or

controls other than the ones indicated in your direct testimony which you instituted to achieve those levels?

MR. FLEMING: Perhaps, John, you should talk to that. I think we have enumerated all the things that we have done; I don't know of anything in addition, but perhaps Mr. Barr can comment if he does.

MR. BARR: Nothing major, other than the ones listed. I think the best thing that can be said is - that it was a fine effort, a combined effort by supervision and employees.

MR. KLEIN: Now, the new equipment that has been listed; is that the only new equipment that you have contemplated in order to reduce the levels of exposure?

MR. FLEMING: No, most certainly not. We have contemplated almost everything, but as perhaps our testimony might have indicated, including building a new plant.

These are the pieces of equipment that we have specifically identified, as practically taking us in the direction we wish to go.

MR. KLEIN: On page 13 of your testimony, under "Fabrication Procedures," the figure .05 percent is used. I would like to know how that figure was arrived at, if you could tell us, please?

MR. FLEMING: Well, I think, as we tried to say, in our statements, the measures that we have taken, with

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the people processing our polymers in their fabrication units, indicate that even at the current levels of monomer content in polymers, we are not finding any signficant amounts, really of vinyl chloride in the fabrication atmosphere.

We believe that the .05 is a significant reduction from levels in many cases already existing, and showing what we believe to be no significant problem.

Furthermore, we believe that this level is achievable. You may recall that the SPI group suggested that there be a target for 1977 of 100 parts per million or .01 percent; we ourselves are not familiar with technology that will achieve that result, and it is our opinion that we don't act wisely in holding out hope for results that we don't see any way of achieving at the moment.

MR. KLEIN: Has anyone in your organization measured the VC release from resin containing .05 percent of the unreleased monomer?

MR. FLEMING: Well, the only way that we have of measured release is in practical operations, such as studies of fabrication plants and so on.

The theoretical study of taking, say a quantity of polymer and sitting it in some kind of a container and measuring the rate at which materials would evolve, this has seemed of less concern to us, and with limited manpower we have tried to put it where we thought the most practical uses and results

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could be obtained.

MR. KLEIN: Now, directing your attention to your fabricating plants --

MR. FLEMING: Yes, sir?

MR. KLEIN: -- have you monitored those plants?

MR. FLEMING: Yes, we have.

MR. KLEIN: And what are the levels that have been shown there, the range?

MR. FLEMING: We have very seldom found any detectable amounts in our tests of those facilities. I perhaps have misstated the case; we have, as I indicated, I think, four such plants. We thus far have monitored two of those four, but the other two, which are remotely located and are very similar in operation but use less PVC in their operations, we in fact have not monitored.

MR. KLEIN: What are the highest readings that you have had at those fabrication plants?

MR. FLEMING: About half a part. Half a part per million.

Now I should point out that that is in the general fabrication area. The plants do have the same kind of considerations that have been mentioned many times recently; the package opening areas, and the heating area, but here again ventilating is what keeps these things down.

MR. KLEIN: Are you in accord essentially that there

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should be some standard to cover fabrication workers?

MR. FLEMING: I do not think the standard of the type under consideration here should cover fabrication plants, no, sir.

MR. KLEIN: Do you think there should be some level below which fabricators should be required to keep the VC exposure?

MR. FLEMING: Well, when people are already performing at an acceptable level, to then require that they do so seems a little superfluous to me.

MR. KLEIN: Well, when you are talking about an acceptable level, what do you have in mind in terms of numbers?

MR. FLEMING: One part per million or less, in terms of fabrication. I am putting that at acceptable levels on the terms being proposed by the Department of Labor, not what I personally think.

MR. KLEIN: Let's talk for a moment about monitoring. There has been some discussion on the question of whether, in order to determine employee exposure it is better to put a monitor on the employee or to monitor the system itself. I would be interested in your comments on that.

MR. FLEMING: Well, I will try to handle that, and then if Mr. Barr wants to supplement my comments, why I will ask him to do that.

We believe that the measure that is really desired,

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the information that is wanted, is how much monomer is passing into the lungs of the individual worker.

Now, there are a number of ways of trying to get at that figure, but I suppose if pressed, perhaps we would say that in our opinion the best measure is by personal monitoring. If pressed, we believe, however, that that personal monitoring is now only practical on an eight-hour basis.

Now, as Mr. Barr's testimony indicated, I think, we found a much more reliable and suitable thing than the short-term tests being proposed by OSHA.

MR. KLEIN: Do you have any underlying data from any experimentations you have done in that area?

MR. BARR: Yes, we do.

MR. KLEIN: Could you make that available to us?

MR. BARR: I can tell you about it here, if you would like me to; it is very simple.

If you take a situation where a plant is operating on what seems to be the same general monitor content -- monomer content in its air as reported by the area monitoring devices, which have not been changed in position or functions, and you compare operators and their eight-hour TWA, and then you compare operators' ten-minute or 20-minute or 30-minute samples, the first thing you find out is that the 10-20-30-minute samples are all over the map. You get a lot of zeros.

Because they vary, either high or low. How

You get a lot of high numbers, and you'll have some in between but not very many. It will be zero or sky-high. Obviously that is not what the total exposure is. And if you don't take enough of those to get a statistically significant sample--and we are going to talk about that number too here in this context--then any lesser number of samples you take is going to be misleading. And this, I'm afraid, is what happened to us and happened to other people early in the game in February and March when they first started taking a few samples here and there.

So, it seems to us that if you want to know what the man has breathed for eight hours, you put a monitor on him for eight hours. If you want to know what's in the air so you can control it and not have him breathe any, then you put the monitors in the area and you measure that and have that do something to the control. So, for those reasons we are proposing that any sensible system will combine the two.

MR. KLEIN: Could yos make the monitoring information in your fabrication plants available to us?

MR. FLEMING: Yes, we can.

MR. KLEIN: Thank you. I believe Dr. Lassiter has a few questions; I have no more at this time. Thank you.

DR. LASSITER: First, Mr. Barr, for a couple of questions.

I believe you made the statement that it's imposs-

ible to guarantee, on page 3, that an employee will not be exposed temporarily to a concentration above a specified level, no matter what that level may be.

Do you consider that this argues for respiratory protection in all workplaces? In which vinyl chloride exposure could occur?

MR. BARR: No, sir, I do not. What that says is that we do not have available to us now the technology to give instantaneous readings on the person.

DOCTOR LASSITER: All right; I was getting to that.

This is in the second paragraph; you made the statement that no matter what that level may be, that there could be temporary concentrations that an employee may be exposed to.

MR. BARR: That is correct.

DOCTOR LASSITER: This, as I understand, would typify a workplace in which you may have leaks, et cetera; is this correct?

MR. BARR: All the workplaces have leaks.

DOCTOR LASSITER: So what I am asking you here then is, if you can't guarantee that all the time you can stay below a given level, the fact that you couldn't even specify what a high -- presumably high level would be, that this would argue for respiratory protection at all times in the workplaces?

MR. BARR: No, sir; it does not follow.

It would only follow if you believed that certain high concentrations were dangerous.

DOCTOR LASSITER: Thank you.

In the next paragraph --

MR. FLEMING: Doctor Lassiter, I wonder if I could give a little more of the underlying thinking behind Mr. Barr's statements?

You can have a work area or space -- let us say theoretically, now -- that is 100 percent free of vinyl chloride. And now in that workspace there is a source of leak.

As soon as that leak occurs, if you allow me to suggest that perhaps the leak is 100 percent vinyl chloride. Okay; at the point of the leak, the concentration of vinyl chloride is quite clearly 100 percent.

Now, as you move away from the leak, the concentration of vinyl chloride will go down, and the rate at which it goes down will depend upon the size of the leak, movement of the air, natural diffusion and many, many other factors.

So what we're really saying is that there is no way, as long as you have a system that has a leak, that at some point, at least at the point of leakage, you have a concentration that you can not guarantee is below any determined point.

DOCTOR LASSITER: Thank you very much for that analogy.

You have mentioned that we do not now have -- that our technology has not provided us with an instantaneous type of analyzer for a worker breathing zone.

Could you tell us something about what might be available in terms of your experience with the total carbon analyzer, in using this as an analogy for vinyl chloride for this type of use?

MR. BARR: Yes; we have used a so-called century estimate -- the OBA, early -- since early in February, and it is a very good instrument, very useful. It has two drawbacks in terms of what we are talking about doing here.

One is that it is too large for a man to carry around with him all day. If we had a miniaturized version of it, it would be great. Perhaps we will get one someday, but we don't have one now. Two, it is a total hydrocarbon analyzer.

The other problem is it is not discrminatory -- Now, in most places that is not a problem, but in some places it is, and particularly if you are going to talk about non-detectable levels, you certainly do have to have a discriminatory instrument.

I will grant you a little bit of background if you are willing to talk in the area of 25; if we are talking about 25 and we find that the natural background in our plant

environments on the Century to be somewhere in the 3 to 8 range, depending on which way the wind is blowing, from what town and what day, then the 3 to 8 is not too much harm to us out of 25. But out of 10 it takes away a bit of our safety factor. And out of 1, we have already had it.

MR. KLEIN: Realizing you could not use it anywhere where you have got organic fumes, if you could perhaps characterize your workplace where you could draw a direct parallel to your reading on the hydrocarbon analyzer with vinyl chloride, do you think this might be an acceptable way to do an instantaneous personnel monitoring, realizing that you might have to, say, carry the thing from place to place for an employee, at least to determine what this employee might be exposed to? As opposed to doing charcoal tube type--

MR. BARR: If I am going to carry a bucket of bolts around, I'd rather have a vapor face chromatograph. I would put either the tube on the Century or I would buy correlate or get some other portable FID.

DR. LASSITER: If you did have available to you an instantaneous reading instrument, if these were available, would a TWA or seeing value best control the total exposure of a worker to vinyl chloride?

MR. BARR: Again, it depends on what you are trying to control.

The TWA will tell you how much he

got in total. The ceiling or instantaneous reading will tell you how much is getting then.

DOCTOR LASSITER: We are talking about total exposure during the day.

MR. BARR: Then if you want to go with total exposure, at least indicate it, you must go with TWA, because instantaneous readings must be integrated before you know what the total exposure is.

DOCTOR LASSITER: We are talking not about determining total exposure, but controlling total exposure.

Do you think a TWA would be better than a ceiling total?

MR. BARR: No. If you want to control exposure, you will do area monitoring. That area may be very close to the employee, but it would still be area monitoring, so that means instantaneous readings.

I do feel, as we said in our testimony, that you need both figures; you need the integrated figure, you need the instantaneous figure.

Otherwise, you can not really have a handle on the problem and know what you are doing with it.

DOCTOR LASSITER: Thank you.

Doctor Kotin, I have a couple of questions for you.

I haven't had an opportunity to look through this study, so I made a few notes. On the basis of your present

knowledge concerning exposure to vinyl chloride and occurrence of angiosarcoma in experimental animals, and the occurrence of this disease in employees exposed to vinyl chloride, do you consider that a causal relationship probably exists between the exposure to vinyl chloride and induction of angiosarcoma into the livers of such employees?

DOCTOR KOTIN: I do.

DOCTOR LASSITER: Can you state at this time that none of the employees examined in your investigation have angiosarcoma of the liver?

DOCTOR KOTIN: I can, within the limits obviously of the sensitivity of our testing methods.

DOCTOR LASSITER: In other words, you are stating that none of the employees examined by you have angiosarcoma of the liver, to the best of your knowledge?

DOCTOR KOTIN: Correct.

DOCTOR LASSITER: Is it possible that some of these employees may have angiosarcoma of the liver and were not detected by your techniques?

DOCTOR KOTIN: Possibly, yes. Probably, no.

DOCTOR LASSITER: What would you have to do to make sure that none of the employees in the examination had angiosarcoma of the liver? That is, would you have to go beyond the biochemical tests for liver biopsy to assure this?

DOCTOR KOTIN: It would depend upon the state of

the cancer. If it were the early circumscribed cancer -- you must remember that the liver is an organ that has a reserve capacity of many 100 percent, and you don't begin to get significant interferences with liver function, particularly when you are dealing with a discrete entity like a cancer, in contrast to total involvement like hepatitis.

So that you can have a cancer sitting in the liver for a long, long time before any of your tests will manifest its presence.

So therefore I would have to answer that the size of the cancer, where it was; if it were a small cancer located close to one of the bile ducts, so that it pressed on it, obstructed it and gave the patient jaundice very early in the game, we would diagnose that very, very early.

If it were in the dome, sitting under the diaphragm, where the excursions of the diaphragm may give the patient some pain with each breath, we might diagnose it early.

Alternatively, if it were seated in the right lobe of the liver, right in the central portion, far removed from any of the things I have described, it could get the size of a golf ball, maybe even a baseball, before liver tests might conceivably identify it.

This is the real problem of the diagnosis of cancer in any visceral organ; when it becomes manifest clinically.

DOCTOR LASSITER: So what you are saying here is

that although these may be the best of biochemical tests available, they would not in all certainty detect angiosarcoma of the liver.

DOCTOR KOTIN: I absolutely agree with you.

DOCTOR LASSITER: Do you recommend the screening protocol you used at Air Products, or do you recommend that the screening protocol you used at Air Products be used by the PVC industry as a whole in screening employees for liver abnormalities?

DOCTOR KOTIN: I do.

DOCTOR LASSITER: And would this be especially true for the alphafetaprotein and the CEA tests?

DOCTOR KOTIN: No; if you will notice, the alphafetaprotein and the CEA tests were second order tests, if you recall.

The alphafetaprotein and the CEA tests, both of which have as their ultimate goal the identity of the cancer prior to the manifestation of other symptoms, like all cancer tests, are fraught with a reasonably high percentage of false positives and false negatives.

We know of many other diseases that give you an abnormal presence of either alphafetaprotein or carcinoembryonic antigen, so that I would be very much surprised to find the positive alphafetarotein or a CE antigen in the absence of some other abnormal findings in the original either 12 or 13

channel tests that you might perform, plus the other routine pheral examinations.

DOCTOR LASSITER: Then you would perhaps recommend these two tests as secondary screening tools?

DOCTOR KOTIN: I would. I would not use them in the first go-around.

DOCTOR LASSITER: Would you make your protocol and the results you found available as a part of the record of the public hearing?

DOCTOR KOTIN: I would be pleased to if it is agreeable.

MR. FLEMING: Yes, of course.

DOCTOR KOTIN: Certainly, I would be happy to.

DOCTOR LASSITER: Did you collect the work history of the employees that you examined in terms of exposure to vinyl chloride at levels that may have been -- for the years of exposure and the levels that may have occurred?

DOCTOR KOTIN: YEars of exposure, yes. Levels, absolutely not.

DOCTOR LASSITER: Could you say anything in general about this employee population in terms of exposure to vinyl chloride?

DOCTOR KOTIN: I think I can submit that for the record. I do know that there are some employees that have been exposed as long as 15, 16 -- maybe 17 years, in the

group. I don't know what the percentage of the total 500 in the two plants would be, but we did at least get a short-term -- a short-term exposure really would be meaningless, but we did place some emphasis on trying to identify those with the longest exposure. And these data are avaialble.

MR. FLEMING: Just in general terms, about ten percent of the employees are over 50 years old.

DOCTOR LASSITER: In your years of experience in the field of environmental induced cancer, and your consideration of the experimental animal data from Maltone and the Bio-Test laboratories, and with knowledge of the employee cases of angiosarcoma, do you consider that an exposure threshold exists for induction of angiosarcoma in humans?

DOCTOR KOTIN: I am glad you said "in humans."

Basically, it is going to take three minutes to give you an answer. The concept of threshold is one that we all always get hung up on.

Now, you really asked two questions when you asked about threshold; you asked is there a threshold for the interaction of a chemical with a molecule in the cell with which it must interact to produce cancer.

For this I believe there is no threshold; I think one molecule of a cancer-producing chemical can transform a normal cell.

But there is also the threshold of the appearance of

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a clinical cancer in the total organism -- mouse, rat, monkey, dog, human being. Very obviously there are thresholds for this. In fact, in the laboratory, under controlled conditions it is because we have been able to expose animals to pure carcinogens at levels which we know will not produce cancers in them, that we have learned most about our concepts of carcinogenesis -- the concept of promotion, the two-stage concept of causation of cancer which would be impossible if it weren't feasible to expose animals to cancer-producing chemicals at less -- at levels below which they develop a cancer in their full lifespan, and that concept is a threshold.

You can even become less esoteric; thresholds are all about us. Two-pack-a-day 20-year smokers -- this is a carcinogenic dose, and what is more, it is a maximum carcinogenic dose, because this is where the susceptibility levels off. If you smoke two and a half packs a day, you are no worse off than two packs, although at two packs you are worse than a pack and a half. Yet only 13 percent of the people smoke -- that smoke, get lung cancer.

And let me come back to the question of angiosarcoma and vinyl chloride exposure. As I said, I believe vinyl chloride causes angiosarcoma. But I also believe that if one looks at the data, as indeed I have at Air Products, one can postulate similarities of exposure in a broad spectrum of individuals, and when you begin to look, in trying to set

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them down in really dealing with a small population, admittedly you find a few in this quinquennium, this quinquennium -- by five year periods of age and so on. Well, it is but obvious that there is a difference in threshold for each of these individuals, just as there is for uranium miners or coke-oven operators and the like.

So again, to recapitulate, from the point of view of threshold, in terms of the total organism, there is a threshold. You can demonstrate this very elegantly in the laboratory models.

From the point of view of threshold in terms of the interaction of a chemical with the cell, there is no threshold. The corrollary of all of this is that you have to have two things to have a clinical cancer: the carcinogen, and then you must have a series of other influences which take this transformed cell -- which is going on in our bodies all the time -- and move it along the road to a clinical cancer.

DOCTOR LASSITER: Then in the case of the animal studies, and what you have just mentioned -- your explanation of induction of cancer thresholds, I assume what we are talking about here is the probability that a given exposure will elicit the given response at the cellular level; is this correct?

DOCTOR KOTIN: Oh, I think so; yes.

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DOCTOR LASSITER: Then based on what we now know about vinyl chloride, is it possible to predict what a threshold of exposure would be which would not produce this disease

DOCTOR KOTIN: Yes, I think it would come -- though it is heresy, having spent 25 years working in the laboratory -- I lean with this as a personal opinion, that the laboratory has just about told us all it can in terms of the carcinogenicity of vinyl chloride.

What is necessary now is the well-designed epidemiological study of the employees exposed to vinyl chloride. Unfortunately, there are no exposure data, as we have heard again and again in the last couple of days, but it is now man, rather than the animal, that is going to have to provide us with the data for a threshold, if indeed, there is a meaningful threshold in the sense of the exposure of the total organism, man.

DOCTOR LASSITER: Well then, from the animal data, would you predict a safe threshold of exposure to vinyl chloride in terms of parts per million?

DOCTOR KOTIN: Well, I am going to say I can not predict it, but that isn't -- because I just don't think the animal data are that informative.

You are asking the data to serve as a basis for extrapolation that is not intrinsic to the data itself. By that I mean that if I say no, I do not believe -- the answer

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to your question is: you can't say that there is a threshold on the basis of animal data, I think we are asking of the data now questions which it can not answer by virtue of what it is.

DOCTOR LASSITER: Thank you very much.

JUDGE MYATT: Before we take questions from the floor, we will take a brief recess.

(Whereupon a short recess was taken.)

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6:20PM

JUDGE MYATT: All right. At this point, we will have questions directed to the Air Products presentation, from the floor, please.

I might suggest to you, since the reporter is down there rather than up here, that you go through the whole procedure of identifying yourself, so that she can get your name for the record. Yes, sir?

MR. BELICZKY: My name is Louis S. Beliczky. I am Director of Industrial Hygiene for the United Rubber, Cork, Linoleum and Plastic Workers International Union.

I will address my first series of questions to Mr. Barr.

What is the age of the appliances which your company has?

MR. BARR: That was given in the testimony.

MR. BELICZKY: I am just asking to get it for my own benefit, since I don't have a copy of your testimony

MR. BARR: The first plant went into operation in 1957; the second in 1959.

MR. BELICZKY: So we are talking about -- someone mentioned the workers' exposure -- somewhere around seventeen years.

Is that correct?

MR. BARR: In our plant, that would be, yes.

MR. BELICZKY: Yes. Again, someone mentioned that

you had ordered special equipment for ventilation in the middle of 1973.

Was there any particular reason that you initiated the ordering of equipment at that particular time?

Was there some information that made you more aware of the problem of vinyl chloride, or was this just a general ventilation improvement of the situation?

MR. BARR: The reason we ordered it was that the old equipment had worn out.

MR. BELICZKY: Was it ventilation equipment?

MR. BARR: Yes, sir.

MR. BELICZKY: What is your procedure at your various plants?

I know your reactors differ in size, and differ in operation, but how do you -- if you do -- leak test, or pressure test a reactor vessel?

MR. BARR: If the integrity of the vessel had been disturbed from the previous reaction -- that is, if a gasket or a valve directly mounted on the vessel itself has been removed for blinding repair, for removal or replacement of your rubber disc; or whatever -- the vessel is filled with water and hydrostated.

MR. BELICZKY: Hydrostatically tested?

MR. BARR: Yes.

MR. BELICZKY: At what pressure?

MR. BARR: One plant, I believe, is 165 or 170 pounds; the other plant, I believe, is ten pounds higher.

MR. BELICZKY: And there is a degree of safety in that. Your reactor operates roughly at what? 145 psi?

MR. BARR: In that area. It depends on the product.

MR. BELICZKY: What is the procedure you use currently -- or have used in the past -- when you have a setup reaction? Let's say a reactor sets up and you have a fair amount of the polymer in the reactor.

What is your procedure in removing it?

MR. BARR: You have to send a man in with [illegible] axes or saws, or whatever tools will do it, and cut it out.

MR. BELICZKY: Currently, are they provided with supplier respirators when they do this?

MR. BARR: No man in any plant goes into any vessel without an air line supplied respirator.

MR. BELICZKY: That is the current practice?

MR. BARR: That is the current practice.

MR. BELICZKY: When you clean a reactor to remove some of the surface coating of the polymer, do you initiate any special kind of ventilation procedure?

MR. BARR: Most assuredly!

MR. BELICZKY: Can you describe it generally?

MR. BARR: It first consists of flushing the vessel out completely and filling it, displacing it, filling a vacuum, letting air into it, and then putting a series of push-pull exhaust systems on it so that air is pushed into it from the top and pulled out and exhausted outside the building. After this, then it is monitored. And once it gets below 50, it is continually monitored until it becomes constant. And then a man goes in with the monitor and with an air line respirator on him.

MR. BELICZKY: Among the things that you sample, in addition to vinyl chloride, do you sample for the polyvinyl chloride dust itself? Let's say in bagging operations or hopper filling operations ot loading or unloading operations, do you ever sample for polyvinyl chloride dust?

MR. BARR: We have some routine sampling around the plant which is carried on by one of our industrial engineers, our safety engineer in the plant; yes, these numbers are taken

MR. BELICZKY: Do you have any recollection of the concentration in so many milligrams per cubic meter of polyvinyl chloride dust that you do encounter in certain situations?

MR. BARR: I personally do not because I do not normally see these figures.

MR. BELICZKY: Is it possible that you could provide this for the record to OSHA?

MR. BARR: If it would be helpful to the Secretary

and if the Secretary requests it, we'll be glad to furnish anything he wishes.

MR. BELICZKY: Thank you. You used the Century equipment periodically; the Century equipment operates. Does that have a slight probe with a tiny hole on the end of it?

MR. BARR: Yes, that's correct.

MR. BELICZKY: Do you ever find that it's not good practice to use the Century equipment in areas where there is polymer dust?

MR. BARR: We have not had that trouble. I recall your asking that same type of question of previous witnesses. We have not seen it. Perhaps we are not that dusty. I don't know. But our sensors have not given us that sort of difficulty.

MR. BELICZKY: What kind of equipment do you use to evaluate the amount of residual polymer that may be in a bag or a drum? Do you use the Century to do that?

MR. BARR: Nor normally, because the Century is not a discriminatory device, and we use it for area checking only. When we are interested in vinyl chloride, we use chromatographic methods.

MR. BELICZKY: You use a charcoal tube?

[Continued on page following.]

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MR. BARR: No.

MR. BELICZKY: Direct sample?

MR. BARR: We take a direct sample of the air and inject it directly into the kinematograph.

MR. BELICZKY: Do you use this vacuum bottle type of procedure for this?

MR. BARR: We either use that, or the large syringe with a valve on the needle and a lock on the plunger.

MR. BELICZKY: All right. The sample, or the residual vinyl chloride in the bag or drum -- I assume that you use a needle system? You use a syringe, and you just inject the needle into a bag or into a drum?

MR. BARR: That is correct. We also use infra red devices where you can pull the sample out directly and go right through the instrument.

MR. BELICZKY: Do you ever use the Vacutainer Tube?

MR. BARR: I am not familiar with that trade name.

MR. BELICZKY: Thank you.

I would like to address the next two or three questions to Dr. Kotin.

In light of some of the information that was made available to many people by Dr. Maltoni, he found, in addition to angiosarcoma of the liver, cancers at other

sites, and damage, probably, to some other organs and tissues, based strictly on animal data. Doctors Peters, Munson, and Johnson presented data today which indicates that there is a possibility of cancer in other organs.

In the clinical studies that you conducted -- the biochemical testing and, also, the physical testing, or possibly X-rays -- did you consider damage to organs other than the liver, or did you also consider other forms of cancer, other than angiosarcoma?

DR. KOTIN: We did complete physical examinations and profiled all of the organs. In fact, our third order of testing included -- as you will recall, I mentioned this -- intervenous pyleograms; upper and lower gastro-intestinal series andgall bladder visualization tests and the like, so we did consider all other possible areas of that abnormality, and the battery that we tested with, that we applied to the employees, would have predictably identified overt disease. It is a question whether it would identify latent disease.

MR. BELICZKY: In light of the cases of angiosarcoma that have occurred in this Country and in Europe, and an indication that there may be a lag period ranging anywhere from, let's say, ten to sometimes 29 years, do you feel that your employees are still at risk?

DR. KOTIN: I think anybody is at risk who is exposed to any toxin, let alone a carcinogen.

MR. BELICZKY: Do you have any feeling about collagen testing or testing for damage to collagens, tests called proline hydroxalase or hydroxyprolinase?

DR. KOTIN: Yes. I have used the test. The thing that bothers me about proline hydroxylase is that it gives you no clue as to cause. All proline hyddoxylase tells you is the abnormality in collagen production as a result of the death of some cells where the cells are being replaced by cheap connective tissue, as it were. And all it can do is give you an indication of the rate of progress of whatever it is that you're testing for. It gives you no clue as to etiology.

Stated differently, whether a person is laying down collagen in his liver from alcoholism, from infectious hepatitis, from thorium, or even from vinyl chloride, this will tell you nothing in terms of the etiology. I would just let you know that there is collagen being deposited.

MR. BELICZKY: Would you consider it as a diagnostic tool or a clinical tool to give you an indication that there is some possible damage?

Would you recommend this as a test?

DR. KOTIN: Emphatically not, because for that much collagen to have been laid down, I find it very difficult to concede that the battery of other tests would not be positive.

MR. BELICZKY: You know how to do the proline-oxo-hydroxylase test?

MR.DBELICZKY: I have done the test on urine. I have not done the enzyme test.

DR. KOTIN: All right. Basically, I am not telling you anything you don't already know.

DR. KOTIN: You have to have some pretty good chologen deposition. And, another thing is that if you do the urinary test, it is not going to tell you where the collagen is being laid down.

You, maybe, have nephrosis going on. You, maybe, have a nephrosclerotic kidney laying down chologens, and so on. That is why I don't think I would use it. It is not truly that specific. Unless you have had some experience, though, to indicate otherwise.

MR. BELICZKY: No. I am not permitted to testify.

JUDGE MYATT: Mr. Cottine.

MR. COTTINE: I am Bertram Robert Cottine, Health Research Group.

Dr. Kotin, you are a Consultant, not a Medical Director for Air Products, is that correct?

DR. KOTIN: I was until I joined the Johns-Mansville Corporation on June first.

MR. COTTINE: So that you did serve for some time on the medical staff of Air Products?

DR. KOTIN: Only as a Consultant.

MR. COTTINE: Only as a Consultant.

DR. KOTIN: I did this while I was Dean of the Medical School and Vice President of Temple University.

MR. COTTINE: Did you review their prior medical and diagnostic protocol before you did your study?

DR. KOTIN: Not to any depth, no.

MR. COTTINE: Were there significant protocols developed at that time?

DR. KOTIN: Well, they have -- as most corporations do -- a First Aid Station with a nurse who kept records.

I don't know how you define "significant".

MR. COTTINE: "Specific", I guess, would be more appropriate.

DR. KOTIN: I think they were specific.

Were they anything like the breadth of the tests I discussed here today? Quite obviously, not.

MR. COTTINE: Did you consider them adequate in frequency and content for acroosteolysis?

DR. KOTIN: I think I might have looked, using a few other parameters.

MR. COTTINE: What were they?

DR. KOTIN: Well, I think I could not answer that, because it would have to respond -- I think it would be in response to each individual case. If a patient came to me complaining of numbness of the finger, or temperature insensi-

tivity, or hypersensitivity of the digits, and so on, I would probably do some vascular response tests and the like.

MR. COTTINE: But the general screening, in and of itself ...

DR. KOTIN: I don't think you screen for Raynaud's disease. Not for acroosteolysis. You don't screen for those.

I would suspect that to screen in a meaningful way, you would probably have to X-ray people every six months. I would be much more concerned with the radiation damage than I would be about acroosteolysis.

MR. COTTINE: Okay. Well, now, as far as hemangiosarcoma is concerned, what type of protocol did they have -- I am now talking about a screening protocol. Would you consider that adequate?

DR. KOTIN: For hemangiosarcoma?

I don't know how you would screen for hemangiosarcoma.

MR. COTTINE: A liver dysfunction.

DR. KOTIN: That is better.

MR. COTTINE: Yes.

DR. KOTIN: No. I think that basically the screening for liver dysfunction was that which is usual in the absence of any suspect hepatoxic agent.

MR. COTTINE: So it would not have been specific to vinyl chloride as a carcinogenic?

DR. KOTIN: There is no test today specific for vinyl chloride.

MR. COTTINE: That's right. But it would not have been sufficient for you to detect the various liver dysfunctions which you feel at least are indicative of perhaps finally diagnosing hemangiosarcoma?

DR. KOTIN: Indicative of liver intoxication. Those tests do not diagnose hemangiosarcoma. If I can indulge in the chauvinism of pathologists, only I and my fellow specialists can diagnose hemangiosarcoma. [Laughter]

MR. COTTINE: Is the protocol you used in examing the workers as a subject of your study recommended for continuing use at Air Products?

DR. KOTIN: Absolutely.

MR. COTTINE: And what is the frequency of that?

DR. KOTIN: This is going to be determined--it was in my testimony and I realize you didn't have a copy. It would vary, but I certainly think that my recommendation will be, depending upon age, level of exposure, annual physicals, in some cases 90 days, in some cases 180 days, but certainly in general it is part of a continuing--into perpetuity would be my recommendation in monitoring the population.

MR. COTTINE: Would you submit those recommendations for the record? That is to say in protocol.

DR. KOTIN: I have been asked by--

MR. COTTINE: Fine. Thank you.

MR. COTTINE: Now, if I may direct my questions to Mr. Fleming.

Did you participate in the preparation of the SPI recommended standard for your Engineering Department, or simply Industrial Hygiene?

MR. FLEMING: We were a member. The Air Products operated as a member of the SPI group.

MR. COTTINE: How did you participate in terms of preparation of their recommended standard?

MR. FLEMING: We had a representative on the Steering Committee, and we contributed the ideas and services of a number of other people in our organization.

MR. COTTINE: Could you specify more particularly?

You made a number of recommendations and criticisms yourself.

MR. FLEMING: As a matter of fact, I personally was not involved in any of those sessions within the SPI personally.

MR. COTTINE: I understand. I am asking you as a Corporate Officer, appearing here on behalf of Air Products.

MR. FLEMING: What are you asking me?

MR. COTTINE: I am asking you: What was the nature of that participation?

Did you send down an engineer?

MR. FLEMING: We sent whatever expertise we thought could assist in arriving at a factually based set of conclusions.

MR. COTTINE: And what was that assistance?

MR. FLEMING: It involved time on the part of Mr. Barr. It involved the activities of Dr. Ross Adams, who is our General Manager in Plastics.

MR. COTTINE: Do you know his background as an engineer?

MR. FLEMING: He is a PhD chemist.

You see, part of this work was done in SPI and part was done in MCA, as you know.

We had on the Research Committee operating in the MCA, Dr. Mayo Smith, a PhD chemist.

MR. COTTINE: Fine. Thank you.

Now, you said that the easy things in progressing towards the SPI recommendation for October 1974 had been accomplished at Air Products.

What is left then?

Is it the engineering and equipment changes?

Is that a correct summation of your testimony?

MR. FLEMING: I think that is reasonably correct.

MR. COTTINE: And how would you identify, more specifically, those changes?

MR. FLEMING: Well, I think we tried to do that in our oral presentation.

We talked about, for example, the replacement of the reciprocating compressor with a rotary vane type unit, which is certainly subject to considerably less leakage.

MR. COTTINE: Were there any other things than those simply found in your testimony?

MR. FLEMING: They are also in the testimony, but we talked about the development work that we are doing, and will continue to do, on solvent cleaning and the like.

MR. COTTINE: Now, these various pieces of equipment which you described, could you specify for the record, with greater particularity, the nature of the specifications that would be necessary?

I don't mean the particular piece of equipment you would need, but generally, when you talk about flanges, there are thousands of flanges. I mean, generally, what you need to come into compliance with that standard. This could simply be a submission for the record, if you prefer.

MR. FLEMING: Yes. I really cannot answer your question with the kind of response you apparently are seeking. The basic criterion in equipment selection, in order to meet an induced emission level is: How well does it do that.

MR. COTTINE: Yes, but you suggested a mode of compliance which you would initiate at your particular work site. I assume that a similar type of process could be used at another plant; that perhaps similar equipment might be necessary.

Now, I think then, following from that, if we could have some assessment of the type of equipment that you feel is necessary, at your state of development, that would have to be installed, so that we could make some assessment of it.

Would that be sufficient?

JUDGE MYATT: That is fine, Mr. Cottine, but I am not going to ask him, or require him to do this at this moment. If you want him to make a submission, listing that for the record, fine. We will accept it.

MR. COTTINE: Fine. I am in total agreement.

Have you been inspected by any Governmental agency for vinyl chloride exposure within the last six months?

MR. FLEMING: Yes, we have.

MR. COTTINE: And these were specifically VCM monitoring surveys. Is that correct?

MR. FLEMING: A VCM monitoring measurement was taken. Yes.

MR. COTTINE: What were the results of that monitoring?

MR. FLEMING: I think, as reported to us -- I am not absolutely certain of this -- but as reported, it was one part-per-million, or less.

MR. COTTINE: You were not supplied with a sampling data sheet then from OSHA?

MR. FLEMING: We were told by OSHA what the result was.

MR. COTTINE: May I directly simply an inquiry to the Department of Labor that that be submitted for the record.

JUDGE MYATT: Do you have any objections, Mr. Klein?

MR. KLEIN: No, Your Honor.

MR. COTTINE: I can provide the Solicitor's Office with the date as well.

MR. KLEIN: Assuming that information is available in one form or another, we will put it in the record.

JUDGE MYATT: All right, fine. Next question.

MR. FLEMING: I should point out, though, that our own opinion is that the reading taken by the OSHA people at that time was very likely in error.

MR. COTTINE: Thank you.

JUDGE MYATT: Next question, Mr. Cottine.

MR. COTTINE: We have heard discussed monitoring and medical surveillance and at least some peripheral discussion of a ppm goal established by your company. Could you indicate how that has developed? In other words, were you aiming, prior to the emergency temporary standard for something in the neighborhood of 250 ppm, or precisely what would you consider the range?

MR. FLEMING: Prior to the emergency standard, we

were attempting to live with the already established standard.

MR. COTTINE: And that was 500 parts-per-million?

MR. FLEMING: Yes.

MR. COTTINE: And you had established no goal below that in terms of your operation?

MR. FLEMING: We saw no reason to.

MR. COTTINE: And the Maltoni data released in January '73 was available to you at that time?

MR. FLEMING: Whatever Dr. Maltoni published was available to anyone who found it and read it.

MR. COTTINE: Did you read that data?

MR. FLEMING: I did not.

MR. COTTINE: Did someone in your corporation read it?

MR. FLEMING: We read what he published somewhat after its publication date. I can't say at what time we had read it.

MR. COTTINE: That did not result in any of the three programs, in the monitoring and medical surveillance or parts-per-million goal?

MR. FLEMING: You are talking about the Maltoni data as if it were definitive, and showed something very definite that led to some concrete conclusion that any moron would have drawn. It just is not that way at all.

MR. COTTINE: Are you suggesting that you dismissed the

data as irrelevant as far as VCM exposure is concerned?

MR. FLEMING: What I am saying is that there are all kinds of reports, on almost everything, appearing in the literature in increasing quantities, all of the time. You do what you can to keep up with that. You try to sort out what is meaningful and, when you believe it is meaningful, you apply it. But there are all kinds of preliminary data coming out, and if you try to draw conclusions from inadequate data, and then do something about it every time someone put out one piece of information, you drive yourself crazy, and you surely would have no good effect.

MR. COTTINE: Have you ever assigned to that data any meaningful position in terms of your policy for monitoring medical surveillance, or your PPM goal?

MR. FLEMING: Certainly.

MR. COTTINE: You have. And did that result in any change?

MR. FLEMING: Change in what?

MR. COTTINE: In either of those three programs.

MR. FLEMING: Well, you must understand that the whole effort that we have made to assess the health status of our employee population, and to improve our operations to the point where we are reducing exposure of our employees---all of these things are based on this whole developing circumstance as we understood it; and, certainly, we were

giving as much consideration to these as we felt was warranted at the time. Our understanding of the importance of all of these events, reports, and so on, has increased as more data has become available, and we have acted in accordance with that understanding.

MR. COTTINE: In relation to the past set of questions did you, or did you not, make any changes with respect to your monitoring, medical surveillance; or your PPM goal?

Now, on the one hand you are telling me that you have assessed the data--

MR. COLLINS: I would like to object to this line of questions.

JUDGE MYATT: You don't even have to object. I am going to cut it off. It serves no useful purpose in this record.

MR. COTTINE: May I be heard on that?

JUDGE MYATT: No. I don't even want to hear you.

MR. COTTINE: Okay.

JUDGE MYATT: It is getting late.

MR. COTTINE: I understand that.

I would like my exception noted, please.

JUDGE MYATT: It may be noted.

Proceed.

MR. COTTINE: How many Air Products plants would be covered by the OSHA permanent standard of VCM, as proposed.

MR. FLEMING: As proposed?

MR. COTTINE: That's right.

MR. FLEMING: All of the plants that I have listed in my testimony.

MR. COTTINE: How many of these plants would have to close down if the permanent standard, as proposed, goes into effect in October, 1974?

MR. FLEMING: Well, as to PVC operations and as to PVC fabrication operations, all of them.

MR. COTTINE: Is there some distinction now between VCM and PVC?

MR. FLEMING: Well, no--I said PVC and PVC fabrication. We have both kinds of plants, as I testified.

MR. COTTINE: And those would be closed as well?

MR. FLEMING: Both.

MR. COTTINE: And, of course, you are not engaged in VCM production because you receive that directly from B. F. Goodrich.

MR. FLEMING: At one plant.

MR. COTTINE: Would you supply any documentation on that, or do you feel that your testimony here is sufficient to support that?

MR. FLEMING: I feel my testimony is sufficient.

MR. COTTINE: Thank you very much.

JUDGE MYATT: Are there any other questions of this witness? [No response]

Ex 23-1000

THE UNITED STATES

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

DOCKET OSH-36

TESTIMONY OF

AIR PRODUCTS AND CHEMICALS, INC.

AIR PRODUCTS AND CHEMICALS, INC.
Five Executive Mall Building
656 E. Swedesford Road
Wayne, Pennsylvania 19087

Greetings --

I. INTRODUCTION

I am Richard Fleming, Group Vice President of Air Products and Chemicals, Inc. I am responsible for the Chemical Group of our company headquartered at Valley Forge, Pennsylvania. Testifying with me today are Mr. John T. Barr, Technical Manager - Manufacturing and Dr. Paul Kotin, M.D., our consultant on VCM medical matters. Also with me are Dr. A. Ross Adams, General Manager, Plastics Division; Mr. T. L. Carey, Vice President of Manufacturing; and Mr. Joseph T. Sebastianelli, Attorney.

Air Products operates two plants for the production of polyvinyl chloride using the suspension process and located at Pace, Florida and Calvert City, Kentucky. Combined capacity of the two plants is approximately 200 million lbs./year, or approximately 3.5% of the total PVC industry. Air Products also operates a PVC compounding facility at Calvert City, and small PVC plastics fabrication plants at Morristown, New Jersey, Costa Mesa, California, Durant, Mississippi, and Homestead, Pennsylvania. In addition, we now operate a plant at Calvert City for the production of a different class of polymers, sold as water emulsions, which also uses vinyl chloride as one of several monomers for a portion of its output and we have a second plant of this type under construction at South Brunswick, New Jersey. The total

number of employees engaged in all these operations, including all service support and management is about 500.

Air Products is a non-integrated producer of PVC. We purchase all of our raw materials and are only very slightly integrated forward into fabrication using less than 2% of our PVC production. We are about 10th in capacity among PVC producers, but a relatively large proportion of our output is in special types of polymers. Our PVC plants have been operating since 1957 and 1959, each coming to Air Products as part of acquisitions of larger businesses, the Florida plant in 1969 and the Kentucky plant in 1971.

Air Products has participated in industry studies of health hazards of VCM and will continue to do so. Our own medical examination program, which will be discussed later by Dr. Kotin, has covered approximately 480 present employees. We have also studied the mortality experience of all employees who have worked in these plants. We have found no cases of angiosarcoma.

Air Products and Chemicals, Inc. is deeply concerned about the question of appropriate protection of the health of its employees and of all those involved in the VCM-PVC industry. We are participating fully in whatever activities we can recognize as worthwhile in developing facts that permit determination as to what that health protection means in practical terms. We believe in establishing and observing soundly conceived regulations designed to assure safe working conditions.

We are also very concerned that unwisely conceived and unnecessarily restrictive regulations not be promulgated. Such regulations work to the disadvantage of all concerned, worker, company, consumer, and the economy as a whole.

II. OBJECTIVES OF TESTIMONY

Thus our purposes here today are as follows:

(a) To present for the public record a resume of our study of the health of our own employee population - and to offer the conclusions our medical consultants have reached from these studies at the present time. This is meant as a contribution to the national study of employee health in the VCM-PVC industry that is so urgently needed to guide the formulation of safe practices.

(b) To offer some perspectives on what we consider some key issues relative to arriving at appropriate regulations.

(c) To provide testimony on what we believe is feasible and workable and why, in the way of regulated occupational exposure.

(d) To offer some detailed comments on the proposed regulation for the consideration of those who will write the final one. These will not be presented orally at this meeting in the interests of time, but will be a part of our written submission.

III. EARLY TOXICOLOGY

In much of the information presented prior to and during these hearings it has been or will be stated by many observers that general concern about human exposures to vinyl chloride have passed through three distinct phases as follows:

Phase 1 - fire and explosion concerns and narcotic effects;

Phase 2 - concerns regarding AOL; and

Phase 3 - concerns regarding carcinogencity.

Phase 1 concerns were the only ones of significance from the inception of manufacture and polymerization of vinyl chloride in Germany in the early 1930's until the early 1960's, a period of 25 - 30 years. During this period, VCM was used as an anesthetic, such was the understanding of its toxicology during this time. A number of toxicological studies made in this period show only minor effects from exposures to what were usually high dosages for relatively short periods of time compared to the more recently published information concerning longer term exposures.[1]

AOL was first observed in PVC workers in 1960-1962 both here and abroad and in about 1966 a causal relation between VCM exposure and AOL was established. Since AOL occurrence

1. Documentation of the Threshold Limit Values for Substances in Workroom Air. American Conference of Governmental Industrial Hygienists (3rd Ed. 1971).

was almost exclusively among reactor cleaners who came into frequent physical contact with VCM, precautions were taken to limit or eliminate this and the incidence of AOL declined markedly. These and other plant and operational changes resulted in lower exposure of operating personnel generally to VCM concentrations.

IV. EXPOSURE EXPERIENCE

Industry conducted toxicology studies, exemplified by those extensively reported by Dow, showed that lower exposure levels were necessary to avoid the possibility of toxicological effects of chronic exposure. Specific standards of 500 ppm TWA and then a 500 ppm ceiling were set by ACGIH and later by OSHA and met by industry.

The actual levels of VCM in plant atmospheres to which workers were actually exposed is not a matter of record. The need for such information was not understood and the instrumentation to readily measure it was not available for most of the period of historical operation. Attempts now to reconstruct historical exposure levels are admittedly crude but they are nonetheless instructive. The lower explosive limit for VCM in air at ambient conditions is 3.6%, i.e. 36,000 ppm. In the phase 1 period this was the absolute upper limit of concern to plant operators. Even with a safety factor of 10, levels of 3,600 ppm would have been tolerated if no

other problems were found or expected. It is reasonable to expect that such levels were encountered at times in early operations by some individuals.

It is very difficult to reconstruct the pattern or frequency of early peak levels of exposure in any reliable way. It has seemed more realistic, and perhaps more pertinent, to attempt estimates of the average, long term continuing exposure to which an individual was subjected. Thus TWA data have been used to characterize the cumulative long term dosage thought to have been experienced by workers in PVC plants.

The Chemical Industry Association of the UK has recently stated their estimates of the <u>average</u> TWA exposure of workers in UK plants. These estimates show the following variation over time:

	Average TWA
1945 - 1955	1000 ppm
1955 - 1960	400-500 ppm
1960 - 1970	300-400 ppm
mid 1973	150 ppm
now	50 ppm

Since the technology and equipment used in UK operations, and the economic and safety considerations concerning VCM loss control were not appreciably different from those prevailing in the U.S. or other parts of the world, one could reasonably expect similar estimates to characterize operations in this country. In fact, it is our judgement that these figures <u>are</u> reasonable estimates of what prevailed, on average, in

this country. Our estimates for our own plants are about the same as this table. Note that these are average figures so that some plants must have been higher at least part of the time. Furthermore, it seems clear that within those plants some individuals probably had even higher exposures.

V. CURRENT SITUATION

The recent liver cancer findings are the legacy of this type of exposure. Each case found to date has involved an individual who has worked through periods of high level exposure by any current day measure, and all have worked for some time in jobs where the highest individual exposures have been encountered.

Thus far the extensive search of the human experience for angiosarcoma among workers in VCM-PVC has turned up 19 cases since 1961. Of these, 13 are in the U.S., found among the employees of 15 VCM plants and 36 PVC plants. Of the 13 cases, 7 have occurred at one PVC plant, 3 at another. A U.S. total of 4 PVC-VCM plants have had known cases. There are thus 47 plant populations who have no record of angiosarcoma although they have lived through periods of exposure well above levels no one would tolerate in the light of current information.

There is a considerable body of animal exposure data to show decreasing hazards with decreasing exposure levels of VCM. Moreover, the human experience in its plants reported by Dow at the February hearing has shown no incidence of angiosarcoma among its

workers from long term average exposures of between 100 ppm and 200 ppm/TWA. Air Products own health studies show one case of ADL and no other health problems related to exposure in our operations to date.

Although exposure levels in fabricating plants have generally been very low, exposures in a few jobs in these plants have historically probably been of the order of 15-25 TWA. Until the recent announcement of the GE wire coating case, and the case of the accountant at a vinyl sheet producing plant there were no reported angiosarcoma cases among fabrication plant employees. As we heard in yesterday's testimony, any relationship between these cases and exposure to VCM remains conjectural at this time. Careful study of the very large body of human experience already available in the history of PVC fabrication operations is clearly warranted and can shed important light on the hazards of relatively low level exposure.

Exposure levels in VCM plants are generally considerably lower than in PVC plants because of the continuous process technology of the monomer operations and the generally outdoor construction of these plants. Only one angiosarcoma case has been found among VCM workers and this man is reported to have worked on very high exposure tasks related to sampling and catalyst tube cleaning. He also worked in PVC for the final year of his working life.

All of these considerations lead to the idea of a relatively safe but readily measurable level of VCM in a work environment.

We therefore support the proposal for a 25 TWA exposure level effective October 5, 1974. As we will show later, we believe that this level is also feasibly attainable, though a difficult and expensive one to continuously meet 100% of the time, as we would hope to do under such a regulation. Lower levels, proposed for later achievement, are much more difficult and much more speculative as to achievement at this time in our view. This too will be elaborated on by Mr. Barr.

VI. EFFECT OF STANDARD ON OPERATIONS

Any level of exposure that is required by a new standard that is below current achievement confronts a producer with essentially three alternatives:

1) Since he does not meet the standard, he can shut down and abandon the business. The economic consequences of this on the producer and his employees are apparent. The effect on his customers depends upon what alternative sources of material they can find. SPI testimony covers this in some detail.

2) He may make changes, involving capital expenditure or otherwise, to bring his operations into compliance. Depending on the severity of the standard this will take more and more fundamental and expensive changes and thus longer and longer times, and may reduce output although not stop it entirely.

3) He may decide to replace his current plant with a new one designed to meet the new standard. This route, of course, requires the most in time and capital money.

Thus far, all producers have been proceeding according to alternative #2. Everyone has obviously done the quickest, easiest, most effective things first. This has permitted most of us to quickly approach conformance to the emergency standard now in effect. I say approach because I do not believe any PVC producer is able to stay below 50 ppm 100% of the time at every location in his plant. I know that we are not, in spite of our most strenuous efforts, and I believe we may be ahead of a number of other producers in measures we have taken.

Because of the volatility of VCM and the internal pressures in PVC equipment, every flange, valve, pump, compressor, heat exchanger, and other piece of process equipment is a potential source of leaks. Much of the equipment must be opened routinely for cleaning and inspection to insure safe operation, and large quantities of air pass through other items of equipment such as centrifuges and driers. There is no one thing to be done to limit VCM loss to the plant atmosphere, there are literally hundreds of leaks or potential leaks to deal with. This should make it clear how hazardous are estimates

of future achievable VCM levels in plant air and how likely it is that excursions in these levels will unpredictably occur from time to time. Replacement of older equipment with newer types, designed with minimum leakage in mind, depends upon availability and deliverability of such replacements. Delivery of even an exhaust fan takes months in the current high capital spending environment. Major equipment takes many more months.

Although we at Air Products are not at all satisfied with our ability to guarantee conformance with the current emergency standard, we support the 25 TWA proposal for October 5, 1974. We need the delivery of new equipment to meet this level but have some confidence that we can meet it. The concept of a ceiling level, and how it is to be measured and administered requires clarification in the proposed standard, and Mr. Barr will cover this in our more detailed comments to follow.

Alternative 3 requires some comment. For any producer of PVC other than one who also produces VCM this is not currently a realistic alternative. Air Products for some time has been attempting to develop an assured source of supply for enough VCM to build a new, modern PVC plant. We are naturally reluctant to do this without such a source. Two years of contact and/or negotiation with every conceivable supplier has yielded nothing of substance. We can forsee no change in this situation for some time, at least until substantial new VCM capacity is announced for merchant sales and is nearing production. No such plant, which takes three years to build, is now in prospect. Under these circumstances, should any significant part of the industry be forced to shut down by unrealistic regulation, greatly increased concentration of the industry will surely result.

VII. VENTILATION CONSIDERATION

Any estimate of achieveable levels in the plant atmosphere is of course dependent on the degree of plant ventilation permissible as well as on the degree to which VCM is released. Virtually all of the testimony presented in this hearing will be based on the basic presumption that very extensive use of strong ventilation is acceptable. This is so because no practical technology exists for the removal of VCM from large volumes of plant air. It seems clear from current information

that this presents no real problems but it must be recognized that unrealistic actions in the way of external environmental regulation can negate practicality just as easily as unsound in-plant regulations.

VIII. FABRICATION SITUATION

Consideration of fabricating operations as potentially regulated ones must also be given. There are sufficient data now becoming available to warrant a judgment that if resins containing not more than 0.05% by weight of uncombined VCM are shipped from the polymer plants that there is no need to regulate warehouses, shipping facilities or fabrication operations. Data to support this will be offerred by Mr. Barr. There are two possible places in fabrication operations that should have some elementary precautions in effect, however. Such precautions seem to be already adequately covered by existing OSHA requirements.

At the point where the PVC container is first opened, the contained air, although quite small in volume, and in absolute VCM content, may be high in VCM concentration. In an impervious container such as a tank car or a silo the concentration will usually be above the corresponding ppm of free VCM in the resin. In a porous container, like a paper bag, the concentration in the contained air will be very noticeably lower. In either case, this air should be exhausted outside of the work area by

appropriate ventillation means. In a similar way, gases evolving from the first heating and exposure of the molten resin should be similarly vented. With these simple precautions the atmosphere in the fabricating work space may be expected to be at levels not exceeding 2 ppm and probably very much lower. TWA's for such plants might be expected to average 1 or less for the employees involved.

We therefore recommend that fabrication facilities processing resins of less than 0.05% uncombined VCM be considered non-regulated areas within the meaning of the proposed standard.

I would now like to introduce John T. Barr, Technical Manager for Chemical Group manufacturing.

Testimony of John T. Barr, Regarding Technical Feasibility of the Proposed Permanent Standard.

These comments are presented for your consideration and are based on the best information available to us at this time. I shall discuss (1) the sources of exposure to our workers, and the methods of exposure reduction which we have used, (2) the methods of monitoring, (3) the programs for exposure reduction which we have in progress, (4) the situation in fabrication plants which we have studied, and (5) a summary of our specific comments on the proposed standard. In addition, we will submit a detailed written commentary on the standard, with suggested changes.

1. Sources of Exposure and Exposure Reduction Methods

About 80% of the PVC which is manufactured in the U.S. today is made by the process which APCI employs, that is, the batch suspension process, and most plants, as do ours, contain a multiplicity of relatively small reactors. These reactors must be opened frequently for charging and cleaning. It is the vapors from these operations, and from the VCM degassing from slurry and dried powder that form the greatest sources of VCM exposure to workers.

The second greatest source is the fugitive emissions from leaks at gaskets, valve stems, pump seals, and other mechanical joints in the piping of the plants. These two sources will continue to be a problem no matter how well maintained or how carefully operated is the plant.

Monitoring of the VCM concentrations taken in our plants during the last week in January disclosed that we had many areas around reactors, pumps, and weigh tanks that contained concentrations in the 200-400 ppm range, with a few isolated points even higher, although the general work space was usually in the 50-200 ppm range. This survey substantiated the results of earlier tests.

At this time, APCI accelerated its monomer exposure reduction program which had been started almost a year earlier. We mounted a major engineering and renovation program, including extensive revision to operating procedures, to reduce the chance of release of VCM inside the building; special retraining of operators; and augmentation of the total ventilation system for buildings and equipment. We instituted the use of airline respirators for reactor cleaning or entering vessels containing VCM, and while doing maintance work that could release VCM. We were fortunate that we had placed an order in the summer of 1973 for much of the equipment needed for the polymer building ventilation improvements, and that this was being in fact delivered in early 1974. Other equipment was obtained from wherever available, and some was diverted from its intended application in other areas for this service. Immediate attention was given to the trouble spots, by the assignment of all available technical and maintenance personnel. This allowed us to reduce the exposures to the point that by the time the temporary standard of 50 ppm

took effect on 5 April, 1974 we were already in substantial compliance. Continued work has enabled us to achieve an average 8 hour TWA in the 20-25 ppm range for our workers in the polymerization building, and even lower for those in other job locations. Once again it must be pointed out that these are average TWA figures and many of our results are above this average.

Moreover, we still are having difficulty in maintaining our work spaces below the present standard of 50 ppm ceiling all of the time since it is impossible to guarantee that a leak will not develop, and that an employee will not be exposed temporarily to a concentration above a specified level, no matter what that level may be.

We want to emphasize the difficulty of a ceiling concept. Technology does not now exist that will give instantaneous readings of VCM concentrations at the worker breathing zone. Therefore, there must be an allowable time period in the standard for the monitoring system to sense a rise in concentration and to warn the employee to put on breathing protection. In addition, the use of that breathing protection must be permitted on a continuing basis when the designated ceiling is exceeded. We cannot understand the practicality or validity of a ceiling standard without such provisions, since it is not reasonable or enforceable, and in the last analysis, we believe that the best basis for the protection of a worker is the control of his total exposure.

Another point which also needs emphasis is that while stopping VCM emissions at their source is clearly the first exposure control priority, the ability to continue to utilize ventilation is essential to overcome the effects of inevitable leaks and losses from any practical system.

2. Monitoring Methods

We have found that two basic monitoring programs are necessary for us to understand completely the problems which we must solve; (1) area monitoring, and (2) the determination of individual employee exposures by personal monitoring.

Area monitoring was first performed in our plants with a portable total hydrocarbon analyzer. This is still being used regularly as a leak detector and to cover those areas which are not covered by fixed point monitors.

We were able to have a 10-point fixed monitor in service in each plant by early April. This is a chromatgraphic device which separates and measures the actual VCM concentration. A second 10-point instrument is now in service, giving us 20 points for our area monitoring in each plant.

Personal monitoring has been in effect since late February using the carbon tube method, and we now have four months experience. We have found that 8 hr. measurements are more reliable and give more realistic data than do the shorter sampling periods which have been recommended.

All three of these instruments have been cross-checked and calibrated against our laboratory chromatagraphs, first by using identical samples on all instruments simultaneously, and second by taking field samples and rerunning them in the laboratory. We have found the correlation to be excellent and therefore recommend that both methods be employed.

3. Programs in Progress

We have completed nearly all of those things which can be done with materials and technology at hand. Further improvements require substantial outlays of engineering efforts, capital, and above all, time to obtain and install the necessary equipment.

We have had on order for almost 5 months now rotating vane compressors to replace the reciprocating machines currently in service in our monomer recovery section. These existing compressors are a source of monomer because of leaks at the shaft seals. The presently promised delivery indicates that we will have the new compressors in service by July of 1975.

We have been working for more than two years, and have spent more than a million dollars, on the development of a solvent cleaning system for the polymerization vessels. This would effectively eliminate the need to open or enter these vessels, and thus greatly reduce the exposure potential. We are not yet completely satisfied with the system, and a recent request for quotations on the required equipment to expand the system from its present level of operation resulted in

estimated delivery times of from two to two and a half years after the order is accepted.

Even standard equipment such as pumps and valves run several months to a year for delivery, and as all of the industry knows, it is impossible to get early delivery on monitoring equipment, apparently because of the large orders placed by governmental agencies. Other quoted delivered times for the type of equipment which we will need are:

pressure vessels:	2 years or more
instruments:	12 to 14 months
field erected tanks:	16 to 20 months
structural steel:	10 to 16 months
centrifuges:	20 months to 2 years.

This situation will deteriorate rather than improve as more companies move to reduce their exposures and we can expect that at least two years will be necessary for any major capital improvements.

Even assuming, however, that major improvements are committed to, we cannot expect to accomplish any further order of magnitude improvements such as we have achieved in the past six months. The very fact that our worker exposure is now averaging 20-25 TWA in itself indicates that many of the readings are above 25, with a few above 50, and we expect that we shall have a very difficult time in maintaining all 8 hour TWA exposure at a level below 25 ppm, if, in fact, we can do it

at all. We can support the SPI proposal of 25 TWA as a goal that we have a reasonable hope of achieving by October, 1974, beyond that we cannot state with certainty the results of technology which is yet to be applied.

4. Fabricators Plant

We believe that PVC fabrication operations do not require regulation under standards being considered for VCM and PVC plants, since exposures to VCM at the fabricators' plants which we have studied are now very low, because very little monomer is present in these plants.

The monomer content of our resins has followed a pattern very similar to that of VCM in the workplace. Levels of 0.1-0.2% by weight in the resin were quite normal as recently as 1973. The steps which were taken to reduce worker exposure in PVC manufacturing plants have produced as a side effect a reduction of the residual monomer. In addition, other work programs have been aimed specifically at this problem, so that at present we can manufacture most, but not all resin containing less than 0.1% free VCM. Air Products has a line of specialty resin, that represent a small portion of its output, with quite low residual levels. The great majority of the general purpose resins, however, representing 65-75% of all our production, now fall into the range of 0.025%-0.075% by weight. We believe that with present programs we can achieve by October, 1975, a goal of 0.05% for all resin at the time of shipment from the plant, and the actual content by the time it is processed will be lower than this.

Our position was substantiated by the results of measurements of the VCM levels in a number of our customers' plants as well as in our own compounding and fabrication operations. We have found these exposures to run no higher than 1-2 ppm, and they are generally well below 0.5 ppm. These results are being obtained while processing polymer of normal monomer content, and with the standard ventilation of the type which is required for ordinary industrial hygienic purposes.

A further important point is that there is no potential for a large release of VCM at a fabrication plant as there could be at a VCM or PVC operation.

Neither do we see any problem in the transportation of PVC. For example, should a 40,000 lb. truck load of PVC containing 0.05% VCM lose even half of its VCM over a several day trip, this would only amount to a loss of 10 lbs. of monomer, which would be so diluted along the route that it would be unmeasureable.

Thus, we can recommend without reservation the exemption from the standards of facilities involved in the handling of materials containing less than 0.05% by wt. uncombined VCM from this standard.

5. Comments on the Proposed Standard

We have prepared a detailed list of objections to the proposed standard as published, and have supplied alternate wording where its is needed. Some of these suggestions differ substantially from other proposals which are being made, and we urge your serious consideration of them. In the interest of brevity, we are submitting these in writing, as Appendix A, and ask that they be made a part of the record of this hearing. A brief summary will be given here.

1. We propose to substitute a limit of 25 TWA, 40 ceiling in place of the no detectable level.

2. Monitoring should include both the work zone and the employee.

3. Respirators may be of the half-face or full face, air supplied type, and shall be worn as soon as possible after it has been detected that the ceiling has been exceeded.

4. Impervious suits should not be required, but clean work clothing be furnished as appropriate.

5. We propose that the permanent standard not apply to PVC, waste streams or finished or semi-finished product, including compound, which contains less than 0.05% by weight uncombined vinyl chloride, or to the transportation or processing of PVC with this level of free VCM.

6. Conclusion

In conclusion, we respectfully submit that the proposed permanent standard fails to meet the basic requirements in the Occupational Safety and Health Act of 1970 either as to necessity, or as to technical and economic feasibility, and that it represents a substantial departure in principle from other standards. Many of its specific requirements are either impossible to meet or are unnecessarily restrictive, and some offer greater hazards than that which they propose to remedy. We therefore request your serious consideration of our comments and suggested changes.

APPENDIX A

SPECIFIC OBJECTIONS

We submit the following specific objections to the proposed permanent standard as published at 39 FR 16896, et. seq., using the indexing contained therein:

1. Background: Vinyl Chloride is not the direct product of oxychlorination, which rather gives 1, 2- dichloroethane that is cracked to VCM.

2. (a)(1) and (2): As stated before, evidence has not been presented that there is no safe level of exposure to VCM, and there is evidence that long term exposure to humans in the 100-200 ppm range causes no clinical harm. It has also been shown that the handling and processing of PVC is safe. The scope of the standard should be changed by striking the word "released", and changing the last phrase to "operations involving the manufacture of polyvinyl chloride." For the same reason change (a)(2) to read: "(a)(2) This section does not apply to the handling, transportation, or processing of PVC or its fabricated products containing less than 0.05% by weight of VCM, or to waste products or streams containing less than 0.05% by weight of VCM"

3. (b)(2): See objection No. 14. This section should be stricken.

4. (b)(3): A closed container which will actually prevent the escape of vinyl chloride gas is not practical, or needed. It is too heavy and cumbersome for practical use, and reopening for additions or removal of materials allows movement of vapors, and it is not feasible for permanent disposal. What is actually needed is a method of preventing contact of the workers with the polyvinyl chloride containing unusually high levels of VCM, and a method of maintaining the vinyl chloride level in the air below the specified limit. The objected to phrase should be changed to: "contact with or spread of the solids contained therein."

5. (b)(4): As was noted earlier, material containing less than 0.05% by weight vinyl chloride is not a hazard. The phrase should be changed to "contaminated means containing more than 0.05% by weight vinyl chloride."

6. (b)(5): See previous objection. Phrase should be changed to: "Decontamination means the reduction of vinyl chloride content to less than 0.05% by weight."

7. (b)(6): As stated elsewhere, the concept of "no detectable level" is impracticable and unenforceable. Such a definition will lead only to endless contention as to whether or not detection had occurred. A reasonable and safe level must be established as the standard, and the detection method must be more sensitive than the established level so that there can be no doubt as to the findings. No specific comments can be made on the proposed monitoring method because it is not published. However, any method can, and will be, improved with use, and limits of detection will be reduced. This is another reason why specific numerical limits must be established, not limits of detection. This section should be stricken in its entirety.

8. (b)(8): This definition is completely impractical. Vinyl chloride will always be present, and there is no evidence of harm from short, low level exposure, or any method of testing for, or treating medically, any results of such exposure. NIOSH on 11 March originally proposed emergency to mean "an exposure which resulted in acute symptoms." Their definition should replace that used here.

9. (b)(9): As noted in the previous comment, there always will be contact with low levels of vinyl chloride in the air, and as noted later, the definition and application of protective clothing needs revision. It has not been established that short-time bodily contact with vinyl chloride vapor is harmful. Numerous animal and human exposures, such as, for example, those cited in "Documentation of the Threshold Limit Values for Substances in Workroom Air," American Conference of Governmental Industrial Hygienists, Third Edition, 1971, pages 277-8, show only mild, reversible clinical changes for very substantial exposures. All evidence to date indicates that if harmful effects occur to humans, they come as the result of long-time inhalation at high levels, and thus efforts to protect workers should be aimed toward reducing inhalation exposure. Following the reasoning used in objection number 8, this should be changed to read: "Exposure means (i) inhalation of sufficient VCM vapor to cause acute symptoms, or, (ii) inhalation of concentrations of vapor above the permitted ceiling for longer than 15 minutes or, (iii) contact of the unprotected skin with liquid vinyl chloride."

10. (b)(10): Because of the suggested change in section (a)(2), this section is no longer needed and should be stricken.

11. (b)(13): In order for clothing to be truly protective against vinyl chloride, a gas, it must be completely impervious and provide whole-body protection. As stated above, no evidence is at hand that skin contact with dilute vapors is harmful. It is implied

by subsequent paragraphs (k) and (l) that the protective clothing spoken of here is not of this type, thus we recommend a change in wording to read, "Protective clothing means clean whole-body work clothing, such as pants and shirt, or coveralls, or a smock." The later applications of this defined phrase assures adequate worker protection. The need for more than normal protection has not been demonstrated except for special tasks.

12. (c) ?: The significance of this portion is not clear and an explanation is requested.

13. (4)?: This appears to be a typographical error and should read (d). In keeping with the changes requested above in sections (a) and (b), this should be changed to read: "(d) Regulated area shall be established where (i) VCM is manufactured, reacted, repackaged, stored, or used, or (ii) PVC is manufactured, or (iii) PVC containing more than 0.05% by weight VCM is processed."

14. (d)(2): It is necessary for service men, contractors' employees, governmental agencies' employees, delivery men, and others to enter regulated areas. The section should be changed to read: "employees and others whose presence is necessary for normal operation of the facility."

15. (e)(2): A minimum of two types of monitoring must be utilized, zone monitoring to alert employees to an excursion above the designated ceiling, and personal monitoring to determine actual exposures. Technology does not now exist that permits instantaneous measurement of actual exposure measured on the person of each employee. The section should be changed to read: "(e)(2) The monitoring shall provide: (i) a record of the VCM content of the general work space, (ii) a method of alerting employees within a period of no more than 15 minutes when the area exceeds the allowable ceiling content of VCM, and (iii) a method of determining the actual 8-hr. TWA exposure of each employee on a regular basis."

16. (e)(3): Details of an observation procedure have no place in a standard, and intrude on the employee-employer relationship. Adequate opportunity for review of an individual's records by himself or his physician and by governmental agencies are provided for in sections (p) and (q). Unlimited observation of calibration and procedures will disrupt and impede the operation, and reduce its effectiveness. This section should be stricken.

17. (f): As stated above, it has not been shown that it is necessary or that it is feasible to operate on a non-detectable standard. Evidence is on record that shows safe conditions exist at levels above even the temporary standard. The use of an indefinite term such as "feasible" makes interpretation of of the standard subject to personal opinion, and thus unenforceable and impossible for compliance. A program such as is called for here is not required in the standard for other suspected carcinogens, see 39 FR 3756. Operation at a non-dectable limit

would require, because of the proximity of other operations in the normal chemical works, wearing of respirators by all employees, and transients, including those in vehicles or walking between areas. This is obviously impractical. This section should be changed to read: "(f)(1) The employer shall undertake a program to assure that employees are not exposed to levels of VCM above an 8-hr. TWA of 25 ppm, nor to instantaneous levels above 40 ppm for more than 15 minutes. (2) Each employer shall provide respiratory protection for his employees in accordance with paragraph (g) of this section."

18. (g): The specification of only full face masks with self-contained air supply is improper. Workers are required to wear safety glasses and many of these are prescription-fitted. Cleaning and adjusting of these is impossible without removing the masks. A better fit and less leaks are obtained with half-face masks. Self-contained units with more than a few minutes air supply are heavy and tiring, and will restrict free movement to and from vessels. Pressure-demand masks require greater exertion than do full-flow units. We recommend that where masks are required that half-face, air line-supplied, full-flow types also be permitted. Our workers have been using this type for several weeks with very satisfactory results. Paragraphs (g)(2) and (3) should be changed to read: "(g)(2) Respiratory protection shall be worn by employees whenever the monitor alarm indicates that the area is above the allowable ceiling, or whenever there is reasonable expectation that an operation will result in the release of VCM into the atmosphere at a concentration above the ceiling. (3) Respirators shall be either half or full-face, type C, air supplied, and capable of operation in the full-flow mode."

19. (h): See objection 11. The clothing and its purpose is not properly defined here. Bodily contact with dust is not known to be a hazard. If protection is needed, it would be for the eyes or lungs. The requirement for a change each time the area is left would be unduly onerous for workers in drying, loading, and bagging areas, as well as for fork-lift drivers, instrument men, and others who move about continually in their work. Exemption from this standard has been requested for resin with less than 0.05% by weight VCM, and other OSHA regulations cover the dust problem adequately. This section should be changed to read: "(h) Protective clothing: (1) Employees working in regulated areas shall be provided with clean work clothing, such as coveralls, shirt and pants, or smocks on a daily basis. This clothing shall be removed upon the last exit of the day from the area. (2) Shower facilities shall be made available to all employees."

20. (i)(3): There is no evidence that non-food chewing products" are dangerous to use in this context, thus this phrase should be stricken from the section. Add the words, "Drinking fountains are not prohibited."

21. (j)(2)(iii): The protective nature of a shower against contact with liquid vinyl chloride is not explained. If the liquid has been in contact with the skin, the indicated treatment is an emollient salve and anti-frost bite treatment, since the boiling point is -13°C., or 9°F. This section should be stricken.

22. (k)(2): Taking sections (k)(2) and (l)(4) together, all persons would be required to wear impervious suits at all times since every operating plant will have some maintenance or vessel entry in progress most of the time. The wearing of full impervious suits itself offers a health hazard, especially in southern climates, because of heat stress and fatigue. Gloves, shoe covers, and water-resistant clothing that allows air circulation, are adequate to protect the worker for vessel entry, and are safer and more comfortable. Section k(2) should be stricken.

23. (k)(3)(4): As written, this would require all product containers to bear this label. Exemption has been requested for PVC with less than 0.05% by weight. The words "more than 0.05% VCM should be substituted for the words "contaminated" and detectable levels."

24. (k)(5): Containers are not defined as to whether this includes all process vessels, reactors, pipe lines, etc., or are inside or outside the regulated area. The label is redundant for inside the regulated area. The statement as to explosive polymerization is incorrect, and the Department of Transportation does not so classify VCM. This should be changed to read: "(5) Shipping containers for vinyl chloride or mixtures containing more than 0.05% by weight VCM shall be labeled: "Vinyl Chloride, Flamable Gas Under Pressure, Cancer Suspect Agent and Anesthetic."

25. (l)(2): This section would prevent shipment of product as written if interpreted literally. It is acceptable only if the definitions of contaminated and closed containers are changed as given above.

26. (l)(4): As noted in the objection to paragraph (k)(2), impervious suits are not necessary and are harmful to the health of employees. This should be changed to read: "(l)(4) In maintenance, cleaning, or repair of equipment or vessels including reactors, employees who may reasonably be expected to be exposed to levels of vinyl chloride above the designated ceiling shall wear respirators, as defined in paragraph (g)(i). Water repellant clothing, and foot covering shall be supplied to those engaged in washing or cleaning vessels for use while in the interior of the vessels."

27. (1)(7)(i): The protective clothing is not defined, and its protective factor is not known. The regulation is impossible to interpret or enforce. The need for skin protection against dilute VCM vapors is not demonstrated, and therefore the paragraph should be stricken.

28. (1)(7)(iii): Various reliable mechnaical warning stand-by devices are well-known, and are in approved use in several states. They have been found to be more dependable than human observers. This paragraph should be ammended by adding (i) "a suitable mechanical warning standby device may be substituted for the observer so long as another employee is on the same operating floor."

29. (n): Exemption has been requested for PVC containing less than 0.05% VCM for the reasons noted earlier in our comments. This section should be changed to read: "(n)(1) Polyvinyl chloride should be transferred or removed from containers only under conditions of local ventilation which will control dust levels as required by general industrial hygiene regulations. (n)(2) Hot operations shall also be carried on under adequate local ventilation."

30. (o): Medical data are not now available to define adequately the proper diagnostic program for existing cases of angiosarcoma, short of biopsy, nor is there concurrance on an early warning test. Consequently, the precise nature of the tests must be obligatory to protect the employee. This section should be changed to read:

"(o) Medical surveillance: Not later than December 31, 1974, a program of medical surveillance shall be instituted and each employee who will work regularly in a regulated area shall be required to take a medical examination in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO). All medical examinations and tests shall be provided without cost to the employee. (1) At the time of initial employment or upon institution of screening, and annually thereafter, a medical history checklist shall be completed by the employee. This list shall include questions concerning; (i) Alcohol intake. (ii) Past history of hepatitis. (iii) Past exposure to potential hepatotoxic agents, including drugs and chemicals. (iv). Past history of blood transfusions, and (v) Past history of hospitalizations. (2) A physical examination shall be performed, which will include: (i) Specific attention to detecting enlargement of liver or spleen by abdominal palpatation. (ii) A serum specimen shall be obtained for screening with respect to the following bio-chemical determinations of liver function. (a.) Total bilirubin, (b) Alkaline phosphates, (c) Serum glutamic pyruvic transaminase (SGPT, (d) Gamma glustamyl transpeptidase (GGTP), (e) platelet count and (f) Additional tests that may optionally be considered for use in screening include:

Lactic dehydrogenase, serum protein determinations, and serum protein electrophoresis. (iii) X-rays of the chest and hands, (iv) tests leading to a conclusion by the physician as to the advisability of working in respirators, and (v) such other tests as the physician may deem appropriate. (3) Laboratory analyses for all biological specimens included in medical examinations shall be performed in laboratories accredited by the College of American Pathologists or licensed under 43 CFR Part 74. (4) A complete and accurate record of the results of medical examinations shall be made and maintained for 20 years past the employees 65th birthday. Upon separation or retirement, the name of the employee shall be transmitted to the appropriate governmental registry, and the employee notified of this transmittal."

31. (p)(i): Medical records may not be disclosed without permission of the person and under present law records turned over to governmental agencies become public property. Thus in (p)(i) the words "medical records" should be stricken.

32. (q): The reporting requirements are excessive. Reporting all detectable amounts released in an area does not contribute to employee protection, and it will not be possible to determine the exact amount in most cases. Fugative leaks at pump seals, gaskets, release from polymer (either waste or product) and VCM from any other sources continually release insignificant but detectable amounts of VCM into the air. The requirement of letters to an employee each time a detectable amount is found is punitive and not constuctive. No good purpose would be served even if it were possible for the employer to comply with these provisions, and the employee and the agency have ample opportunity to see the monitoring results. This form of notification is not required in other carcinogen standards. This paragraph should be changed to read: "(q)(2) Emergencies shall be reported in accordance with this paragraph. --- (2)(ii)(A) An estimate of the amount of material released, if available, - - - "Paragraph (q)(3) should be stricken in its entirety.

23 C
1031

Air Products and Chemicals, Inc.

CHEMICALS GROUP
Five Executive Mall, Swedesford Road, Wayne, Pa. 19087

July 12, 1974

Mr. Julius Jimeno
Hearing Management Officer
Vinyl Chloride Hearings
U.S. Department of Labor
1726 "M" Street, N.W.
Room 200
Washington, D.C. 20210

Re: OSHA Hearings on Vinyl Chloride

Dear Mr. Jimeno:

In connection with the above referenced hearings, Air Products and Chemicals, Inc. submits herewith for the record the statement of Dr. Paul Kotin regarding the results of the medical program at our PVC plants. This statement was designated Exhibit 23-C by Judge Myatt.

This will also advise that Air Products will be providing further materials and comments for the record prior to August 23, 1974.

Should you have any questions, please feel free to call (215) 687-6150.

Respectfully yours,

Joseph T. Sebastianelli
Attorney

JTS:lj

Enclosure

cc: Dr. Paul Kotin

EXHIBIT 23-C

TESTIMONY OF DR. PAUL KOTIN
REGARDING MEDICAL RESULTS

This is a report of the results of the screening of present employees of Air Products and Chemicals, Inc., who are engaged in the handling of vinyl chloride, and of the results of an examination of death certificates of those PVC employees who left the company or who died while employed.

I was employed as a consultant by Mr. Richard Fleming, Group Vice President, Chemicals Group, of Air Products and Chemicals, Inc., in early February 1974 for the specific purpose of establishing and conducting a medical evaluation and surveillance program for employees exposed to vinyl chloride. As a first step physicians were identified in the two areas where APCI has VC operations. Dr. William M. Blalock of Paducah, Kentucky, and Dr. Barkley Beidleman of Pensacola, Florida, agreed to serve, and in consultation with them a medical examination protocol was developed and carried out for employees in plants at Calvert City, Kentucky, under the supervision of Dr. Blalock, and at Pace, Florida, under the supervision of Dr. Beidleman.

Both physicians are certified by the American Board of Internal Medicine. Dr. Blalock is a specialist in gastroenterology and hepatology, and Dr. Beidleman is a member of a large medical group with specialists in gastroenterology and hepa-

tology. Following several meetings between myself and the two physicians, a screening and review procedure was adopted for the APCI employees at the two plants. Special emphasis was placed on identifying and specifically testing for the two diseases for which there were demonstrated associations between VC exposure and disease--acroosteolysis and angiosarcoma of the liver. These areas of emphasis were part of a complete review of each patient which included the following:

At the first level, a complete and detailed medical history was taken on each employee. Afterward a physical examination and a series of x-ray and laboratory procedures were performed as follows:

- chest x-rays
- hand x-rays
- complete blood count with platelets
- blood urea nitrogen (BUN)
- uric acid
- phosphorus
- calcium
- alkaline phosphatase
- total protein
- albumin
- bilirubin
- cholesterol
- globulin
- chloride
- glucose
- triglycerides
- serum glutamic oxalacetic transaminase (SGOT)
- lactic dehydrogenase (LDH)
- serum glutamic pyruvic transaminase (SGPT)
- alpha fetoprotein (AFP)
- carcinoembryonic antigen (CEA)
- gamma glutamic transpeptidase (GGTP)

One or two of the enzyme determinations varied in Kentucky and Florida reflecting the immediate availability of laboratory resources. Tests showing abnormal laboratory findings in any employee were repeated to assure their authenticity. In addition to repetition of the preceding tests when indicated, the following additional tests were performed on employees:

completion of enzyme profile
prothrombin time
carcinoembryonic antigen (CEA)
alpha fetoprotein (AFP)

The persistence of abnormal laboratory findings in the original screen or the presence of signs and symptoms suggesting liver toxicity was followed by a further reexamination of each employee with each being handled on an individual basis. Liver scan and possible liver biopsy comprised the last level of examination.

At Pace, Florida, 201 employees were tested, and 13 employees were found to have test results which varied from established norms. All these 13 employees were retested. Four employees had normal results on retest. Three employees had persistent minor variances which in our opinion did not require further testing at this time. These employees are scheduled for retesting in 90 days to determine their persistence. Liver scans were performed on six employees, all of which were normal.

One case of acroosteolysis was found during the examination, and this employee has been removed from the polyvinyl chloride operation.

At Calvert City, Kentucky, 291 employees were tested. On the initial tests we found 97 employees who had findings which varied from recognized norms. Equipment malfunction was suspected and verified, and upon retest 29 employees showed persistent abnormalities. These 29 were scheduled for immediate retest. Sixteen employees showed persistent equivocal variations and as in the case of Pace, Florida, they are scheduled for retesting in 90 days.

Of the 13 employees with persistent abnormalities who were retested, six showed findings which dictated more complex and increasingly sensitive and diagnostic test procedures for liver physiology and anatomic state. The six employees were examined by intravenous pyelogram, upper and lower gastrointestinal series, gall bladder x-ray, repeat chest x-ray, complete physical reexamination and liver biopsy. The results were as follows:

Two cases of Gilbert's disease (a benign hereditary hyperbilirubinemia), one case of intrahepatic gall bladder (a congenital abnormality) with gall bladder disease, one case of chronic gall bladder disease with coexistent persistent hepatitis, one case of chronic persistent hepatitis and one case showing no abnormalities.

I have also examined all the available death certificates of former employees who had been engaged in the manufacture of polyvinyl chloride and who died either while working for or subsequent to leaving the company. I was unable to identify any relationship between the causes of the deaths and exposure to polyvinyl chloride in their work environment.

Throughout the entire testing and examination programs at both APCI plants, there were constant discussions between the physicians on site and me, some on a daily basis at times. In addition, I have been to both the plants in Florida and Kentucky and have personally reviewed the records with the local physician.

I would conclude at this time that except for the case of acroosteolysis discovered in an employee in the Florida plant, the results of the screening comprising medical and environmental history, x-ray, physical examination, laboratory tests and where indicated liver scan and biopsy, no findings or diagnoses were made which identify vinyl chloride as the causative agent or mechanism. More specifically, we can state at this time that no cases of angiosarcoma have been identified.

Paul Kotin, M.D.

24(2)
1037

ENGINEERING AND CONTROL PRACTICES

K. H. Oelfke
The Dow Chemical Company
Freeport, Texas

Good morning, my name is Karl Oelfke. I am Production Manager at the Texas Division of Dow Chemical U.S.A. My area of responsibility includes the manufacture of vinyl chloride at the Texas Division. In addition, I am responsible for the coordination of vinyl chloride production techniques and technology for The Dow Chemical Company on a world-wide basis.

I would like to speak on Engineering Controls and Manufacturing Practices in both the production of vinyl chloride monomer at our three United States manufacturing sites and the copolymerization of vinyl chloride monomer at our manufacturing site in Midland, Michigan.

The first part concerns vinyl chloride monomer (VCM) manufacture.

This is an aerial view of our oldest currently operating VCM plant in our Texas Division at Freeport, Texas. Commercial scale production of vinyl chloride was started here in 1948. Over the years, through what we have called incremental expansions, production capabilities have been increased by some 400%. You will notice that there is little separation of equipment and the close proximity of the control room to the processing area. The control room is at the middle left of the picture.

You can get some idea of the size of the plant by noting the sizes of the cars in the photo.

Our second monomer plant came on stream in 1958 and is located in our Louisiana Division at Plaquemine, Louisiana. This plant has been incrementally expanded over the years and production capabilities have been increased by some 1,000%. Again, as a result of these expansions, you will note the congestion of equipment, but you will please also note the congestion is less than that shown on the previous slide.

Here we have our most recent vinyl chloride monomer plant located in our Oyster Creek Division at Freeport, Texas, and started in 1969. The most recent plant layout criterion was used at this plant and congestion is minimal. Here the control center is located at an increased distance from the process area.

I'm sure that if we were to design another vinyl chloride plant today, even more thought would be given to plant layout and design.

In earlier years, more concern had been for the hazards of fire and explosion of vinyl chloride. These hazards were the main causes for greater separation of equipment.

Typical of this concern is illustrated by flammable gas detector

alarms which are strategically placed in the plants to alert personnel in the event of a major leak or spill.

One other thing you might have noted is the trend in recent years toward large single "train" units rather than several smaller "trains."

Economically, this can be shown by the generalized formula that indicates that the capital requirements for a plant twice as large as the base unit is 2 to the .6 power. Thus, for 2 small plants, the capital required would be 2 x the base unit, but for a plant twice as large as the base would only cost 1.52 x the base unit. Capital abandonment of an existing plant in favor of a new facility of the same size and essentially the same technology is generally not done in the industry. Economics do influence this decision, such as the reduction in cost of manufacturing as the result of decreased maintenance cost, improved manpower, utilization, improved raw yields and lower freight costs.

From a health standpoint, these large single "train" units considerably reduce emissions because of the fewer number of pieces of equipment.

What have engineering controls and techniques accomplished over the years in vinyl chloride plants, other than the large single train concept? And, how can these relate to vinyl chloride emissions in the workplace?

Let us consider for example, vinyl chloride recovery. In the thermal dehydrochlorination of ethylene dichloride, the cracking furnaces operate with a outlet pressure range of 20 to 400 pounds/square inch gauge. The lower pressures are usually used in the older plants and in plants that remove the by-product hydrogen chloride by absorption. The gases must then be compressed for purification. These types of systems are no longer being built in the more industrially developed countries because of the expense of operation. Reciprocating compressors without packing purges as the first generation, with packing purges as the second generation are being used in our oldest plant. Centrifugal compressors are being utilized in our second generation plants. One of these (a fairly recent technical development) can replace a number of reciprocating compressors, but here again, size and economics dictate any replacements. One plant with which I was associated some years ago replaced five 150 horsepower reciprocating duplex compressors with a 1,500 HP centrifugal compressor when the capacity of the plant was doubled. Even though the five 150 HP compressors

were high maintenance items, there was no way to economically justify replacement by a centrifugal compressor. Potential leaks are reduced many fold using centrifugals instead of reciprocating. Elimination of the compression step is the best solution and this has been accomplished at our most recent plant.

Okay, new plant design and construction has the potential for significantly reducing vinyl chloride exposures in the work-place through such things as plant layout and elimination of equipment. However, from the pictures you have seen that the plants are large and complex with many valves, pumps, and flanges. Consequently, the complete elimination of leaks even in a foreseeable new plant is not technically feasible.

What can be done using engineering control and workplace practices to reduce emissions in existing vinyl chloride monomer plants? First, I would like to emphasize that essential to engineering controls and workplace practices is the identification of problems through workplace monitoring. This can be accomplished by analyzing grab samples of air from various locations, by using personnel monitoring techniques based on carbon adsorption, carbon disulfide extraction and gas chromatography, and by area monitoring. Using these techniques, problem areas were identified. To illustrate what can be done, I will now describe several of

these problem areas and the engineering and work practice methods used to reduce emissions.

Tank Car Loading - It has been industrial practice for many years to gauge tank car innage on pressure cars using vented slip tubes as shown here. The level of the liquid in the tank car is determined by observing for liquid or gas flow from this tube. Freight bills are based on weights of products shipped. Pressure car minimum rates are calculated for 98% of allowable. For this reason, we want to fill tank cars between 98 and 100% of allowable. These gauging devices are set when the temperature of the vinyl chloride inside the tank car has been determined. Normally they are set at 90% of allowable so that when the car has been filled to that level, the loading person can see that the loading is almost finished as the vinyl chloride liquid spewing from the opening creates a short-lived fog (but an emission and potential exposure point). He then readjusts the slip tube to 98% level and tops off the tank car. Even though the 8-hour TWA was below 50 ppm as determined by personnel monitoring, steps are being taken to eliminate this emission. For the long-term solution, magnetic gauging devices are being secured and installed. It is estimated that all of the vinyl chloride tank cars that Dow fills will be equipped with this type gauging device by the end of 1975. An interim solution is being sought at this time. Tests are being conducted using a temperature sensing device in a closed loop

system. This device has had limited testing, but it looks very promising. Disconnecting loading and vent lines from tank cars was another exposure problem. The exposure potential has been lessened through purging the liquid and vapor lines into the tank car with nitrogen.

In-Plant Sampling - Process and quality control samples are a must in the vast majority of chemical production plants. On stream analyzers are the preferred method if at all possible. In some analyses, on stream analytical technology has not been developed. Sampling of the process streams has to be done. Again, with personnel monitoring as our guide, these problem areas were brought to our attention. This is a picture of the old method, the picture was posed. Here we see a closed loop sampling system developed to decrease potential personnel exposure. Both cylinders are evacuated at the laboratory. (The vacuum pump vents to a hood stack.) The sample cylinder is at the bottom, the waste cylinder is at the side. Vinyl is purged from the liquid line at the top, through the cross and out the flexible line at the left. The flexible line is closed and the sample cylinder filled. The valves are blocked from the liquid line and at the cylinder. Prior to disconnection, the waste cylinder (under vacuum) is opened to evacuate the sample header. Considerable potential exposure was eliminated.

Analytical - Personnel monitoring results of our laboratory personnel caused us to study more in depth the job make-up. Wet methods of analysis at one time were performed in the laboratory, but outside the hood. As a result of the monitoring, these analyses are now performed under the hood. Further monitoring indicated that this method of transfer was not satisfactory (hood door raised), although better than previously experienced. This is the method we now use (hood door closed). Unused sample portions are returned to the process.

As we worked on our areas, even though exposures were not necessarily being experienced (they probably were) other problem areas were seen.

In-plant - Header systems such as this pump drain line, reboiler drain line, and vapor recovery units are being installed to return vinyl chloride containing streams to process when maintenance work must be performed. At present, only that equipment requiring frequent maintenance is so headered, such as pumps, reboilers, and filters. Operating procedures were changed to require purging of liquids from lines using nitrogen prior to maintenance.

As you have seen, engineering controls and workplace practices can reduce the potential exposures of our employees working in monomer production, but again I should emphasize that a monitoring system is essential to locate the problem areas.

What about vinyl chloride exposures in polymerization plants? What has Dow done to reduce the exposure potential?

Our most recent polymerization plant in Midland, Michigan was constructed with separation and protection of the major processing phases in mind to minimize potential capital loss. The separation also tends to reduce the potential personnel exposures. Compare this most recent installation with the original plant. You will note the original plant was completely inside a building, while the newest plant utilizes more open construction, even though it is built in the cold North. Vinyl chloride is unloaded into a tank farm some distance from the processing area.

The new polymerization areas are highly automated, using sophisticated computer equipment. The areas were designed and constructed to include: no processing system open to the atmosphere; minimum monomer storage in the polymerization area; minimum number of monomer transfers; no routine opening of monomer lines; larger capacity equipment and a minimum number of vessel openings and entries. We are also testing canned or sealless pumps.

The polymerization control rooms are pressurized with fresh air and are continuously monitored for vinyl chloride.

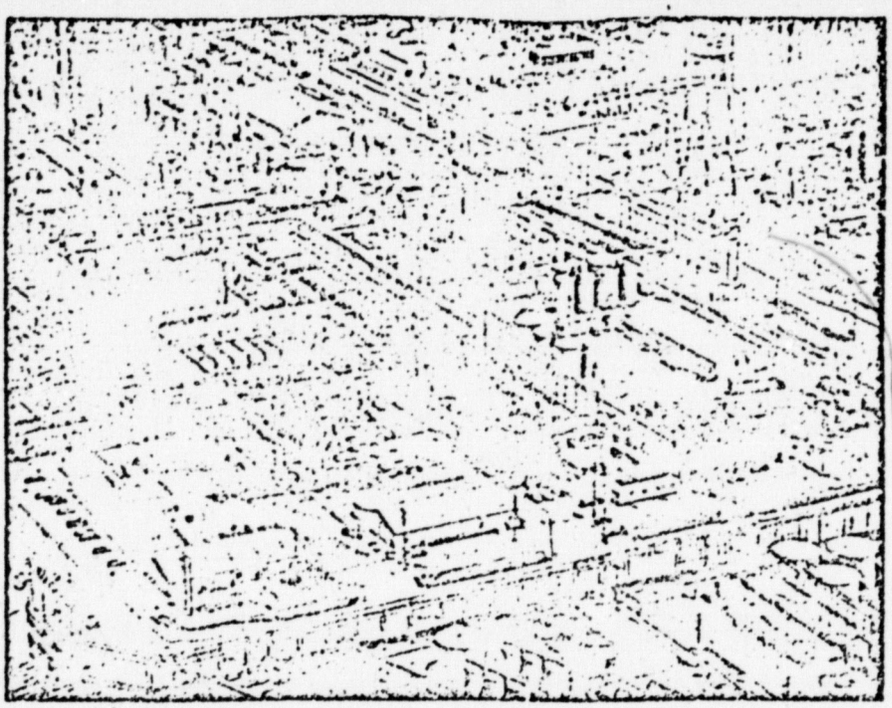
Extensive inline or onstream instrumentation is used (this is a conductivity cell) to minimize the need for taking process samples containing vinyl chloride. Where monomer samples are required, a closed loop system is used. Here the sample cylinder (still containing the residue from the last analysis) is connected to the liquid line on the left and to a vacuum line on the right. The valves are arranged to flow through the cylinder. The cylinder valves are closed as well as the sample point. The vacuum line is opened to the left end of the cylinder. This allows both ends of the cylinder to be evacuated prior to removing it. This is in contrast to past sampling procedures (this picture was posed).

At the present time, even with the best designed system, it is occasionally necessary to open lines and equipment which have been in vinyl chloride service. In these cases, piping provisions have been made to allow draining the monomer, flushing with a non-hazardous material and purging with an inert gas before opening to the atmosphere.

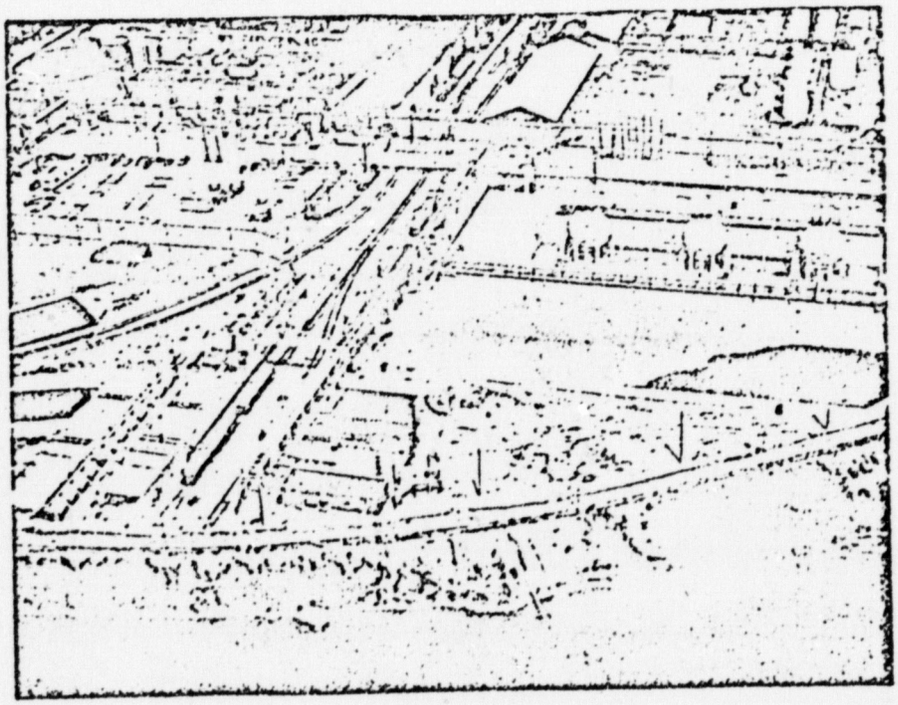
In our polymerization plants, just as in our monomer plants, lower explosive limit alarms are located throughout the plant to detect major spills and leaks should they occur.

As will be presented in our testimony on monitoring, we've

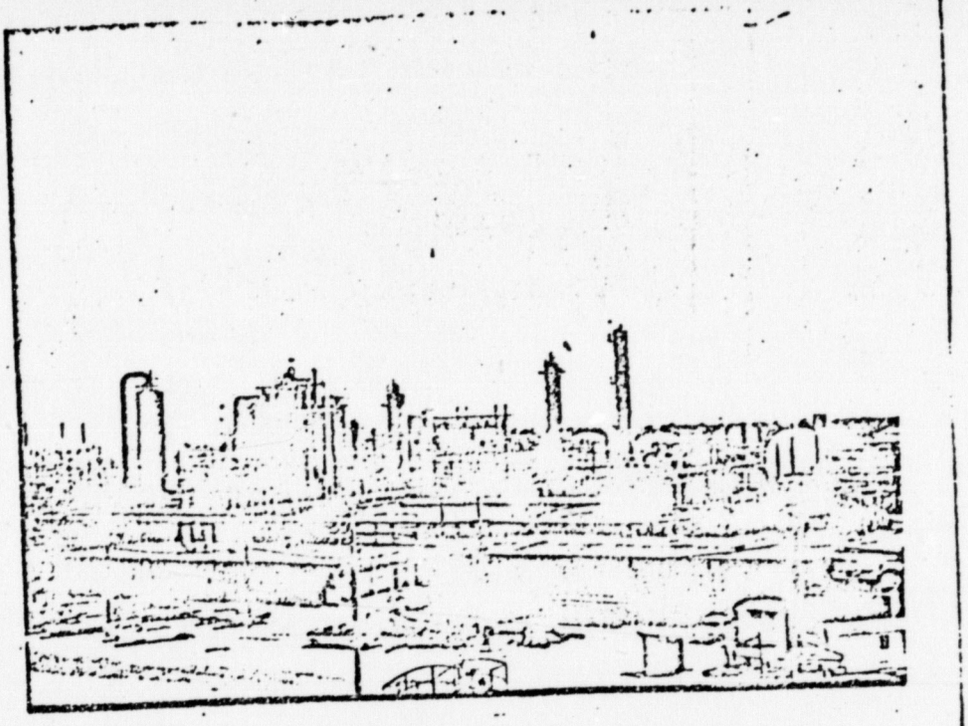
come a long way in reducing vinyl chloride exposures of our employees through engineering techniques and workplace practices; and, as technology improves, we will further reduce these potential sources of exposures. However, from a practical standpoint, the technology does not now exist to eliminate all sources of emissions in these large complex plants.



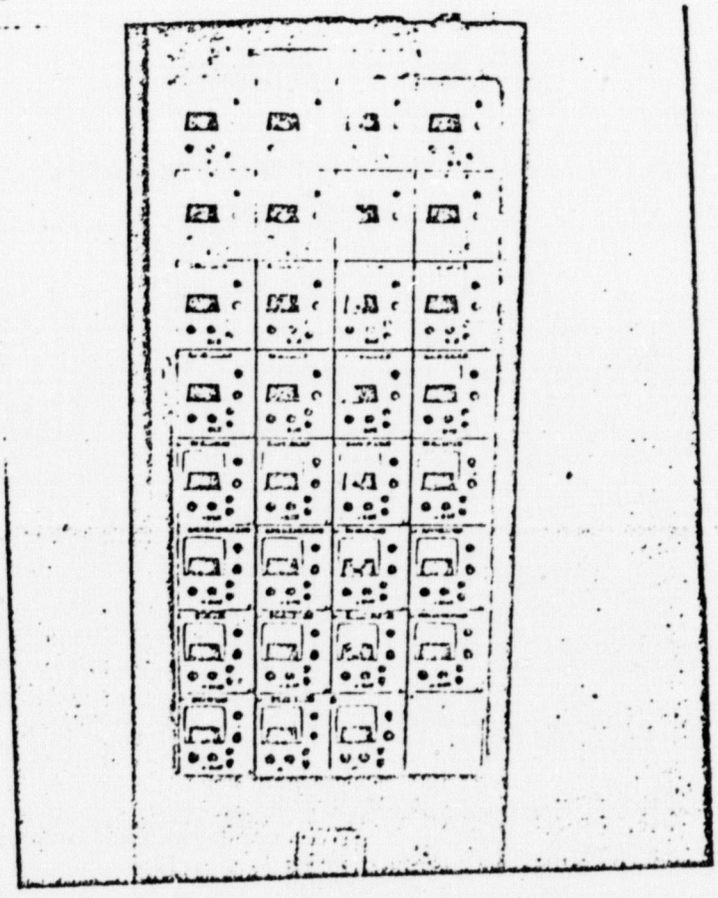
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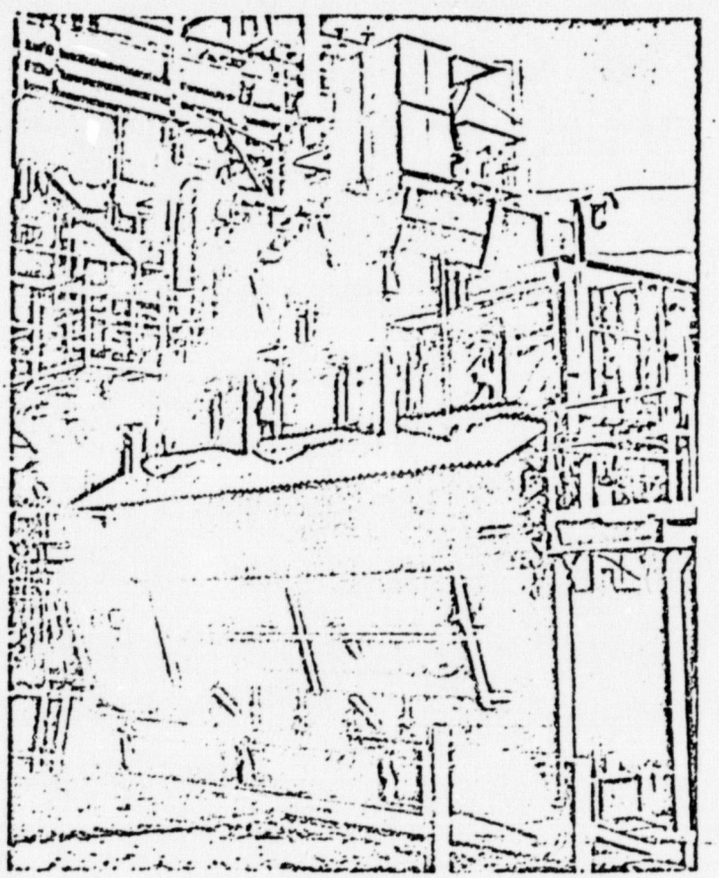
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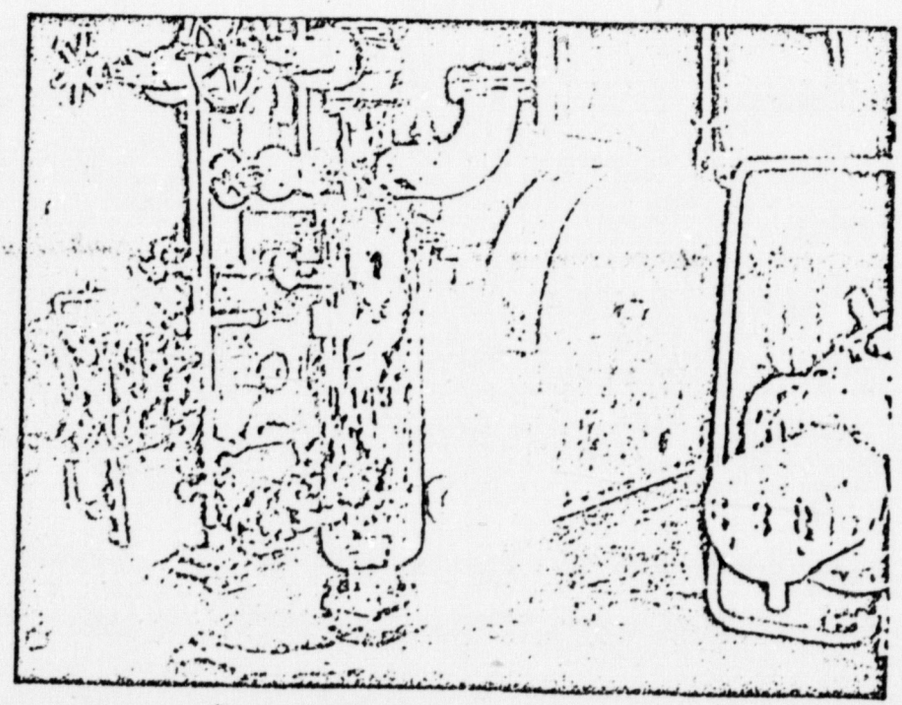
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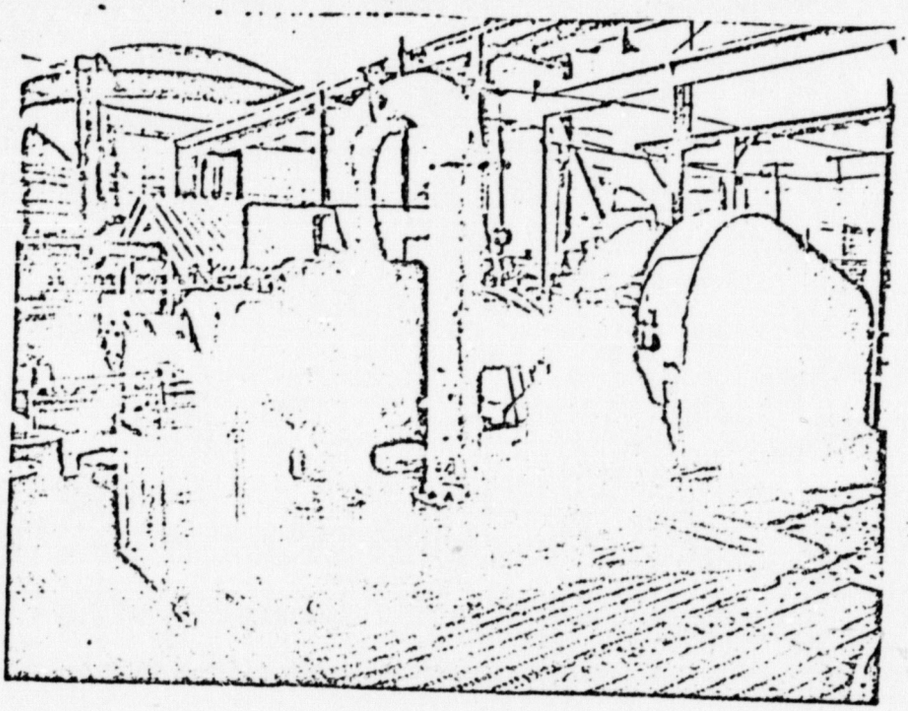
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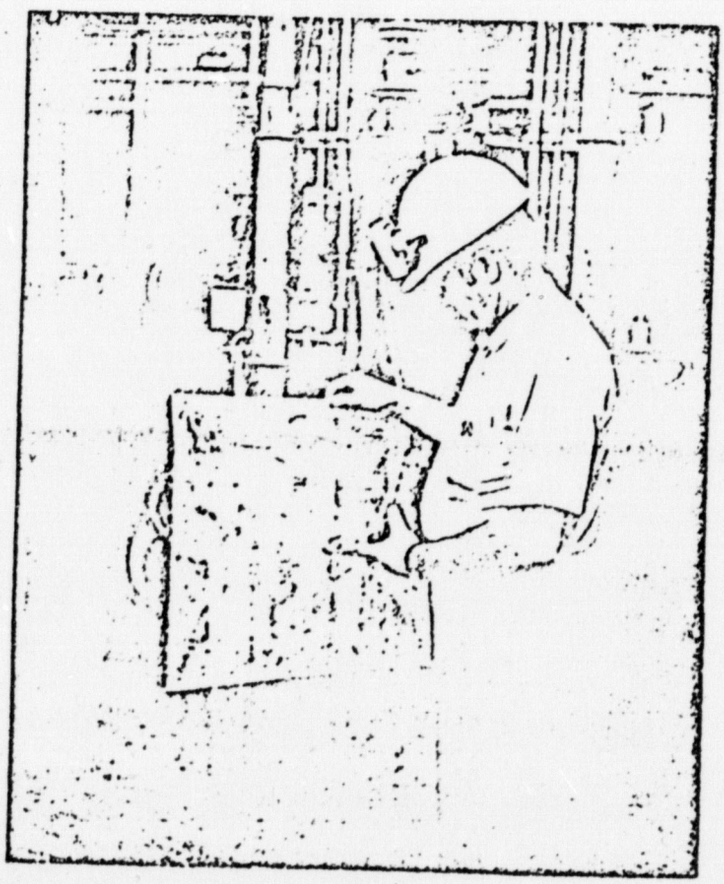
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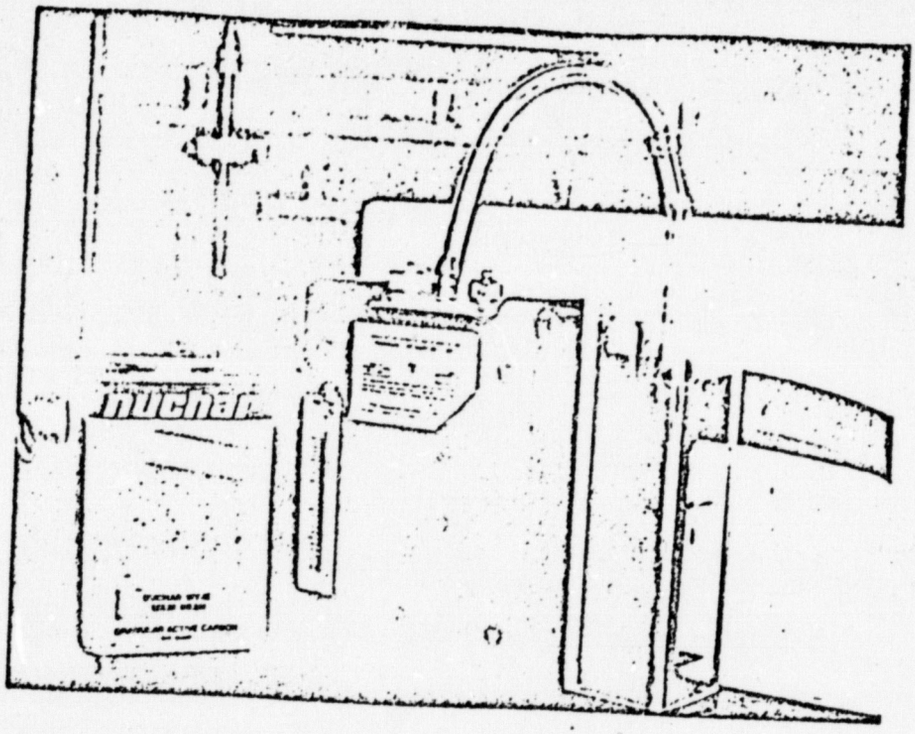
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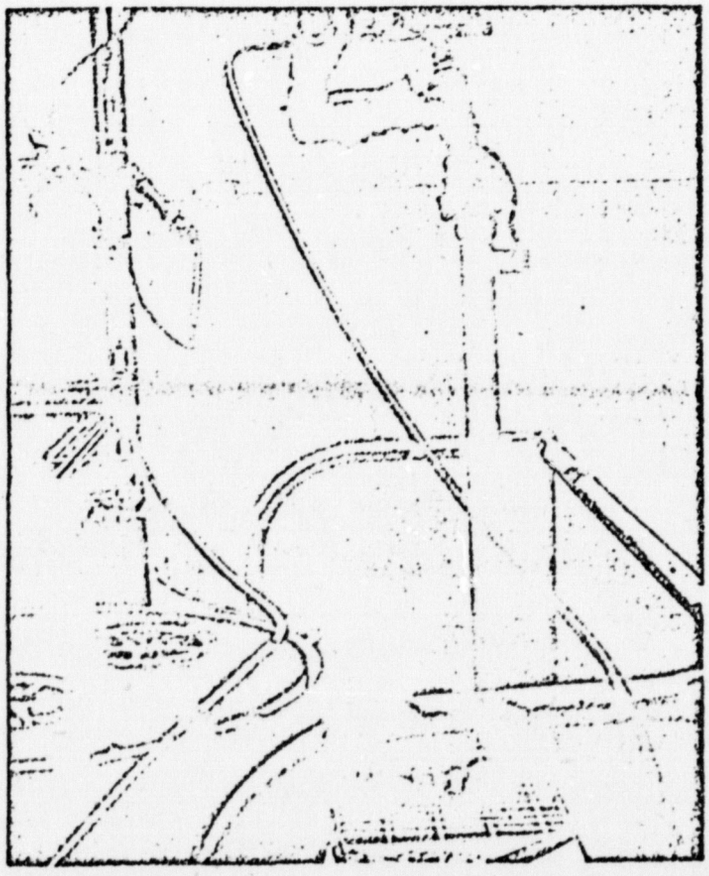
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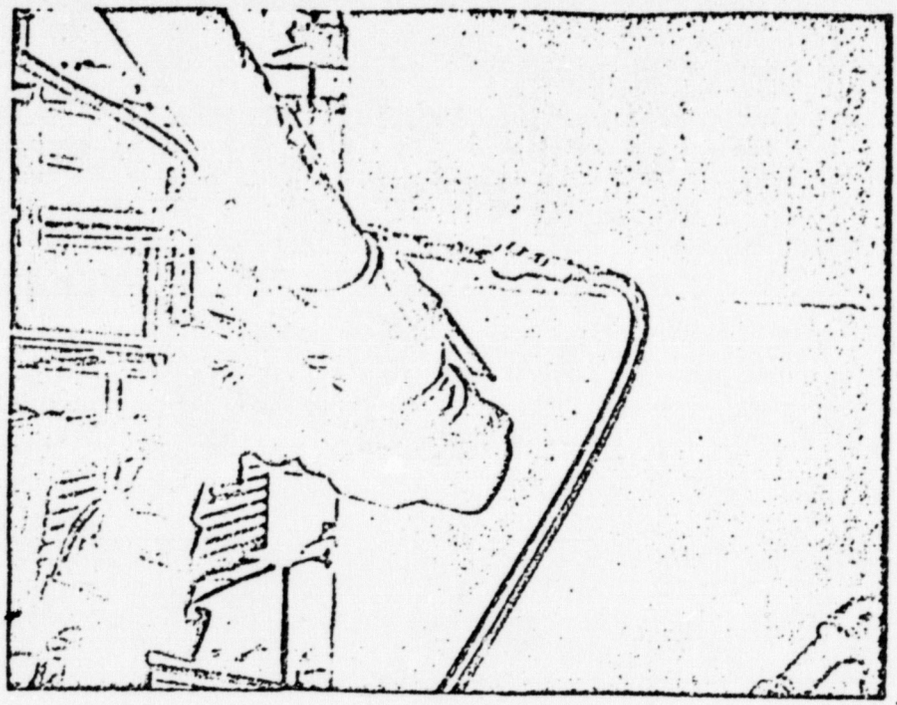
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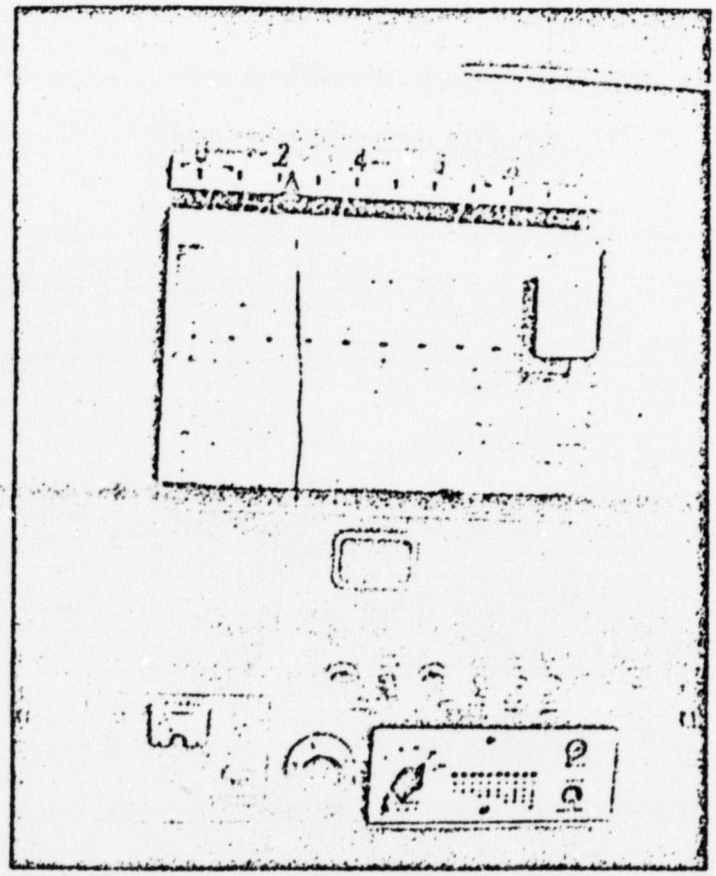
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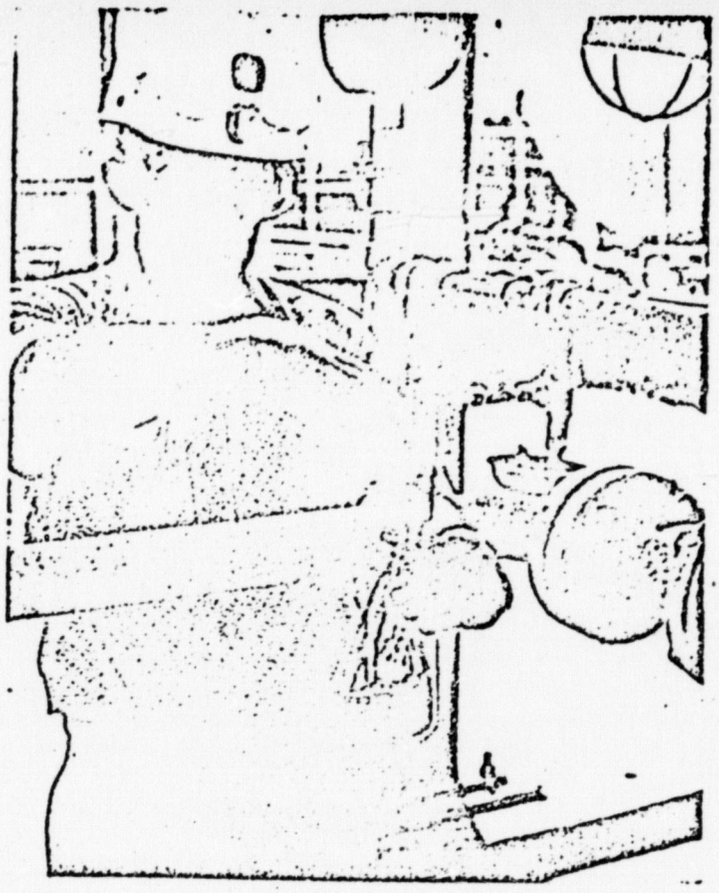
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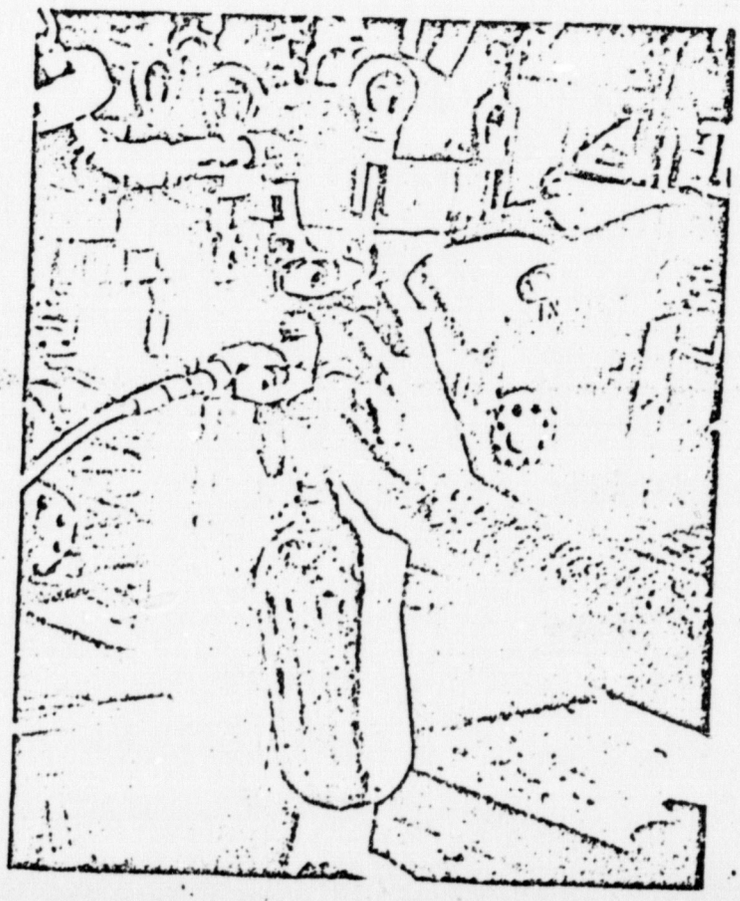
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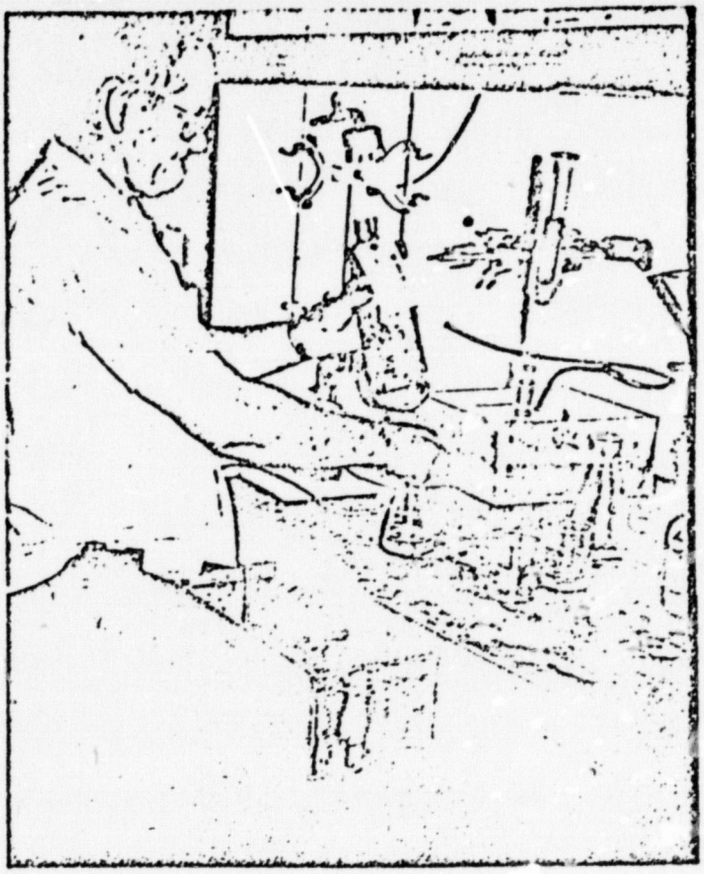
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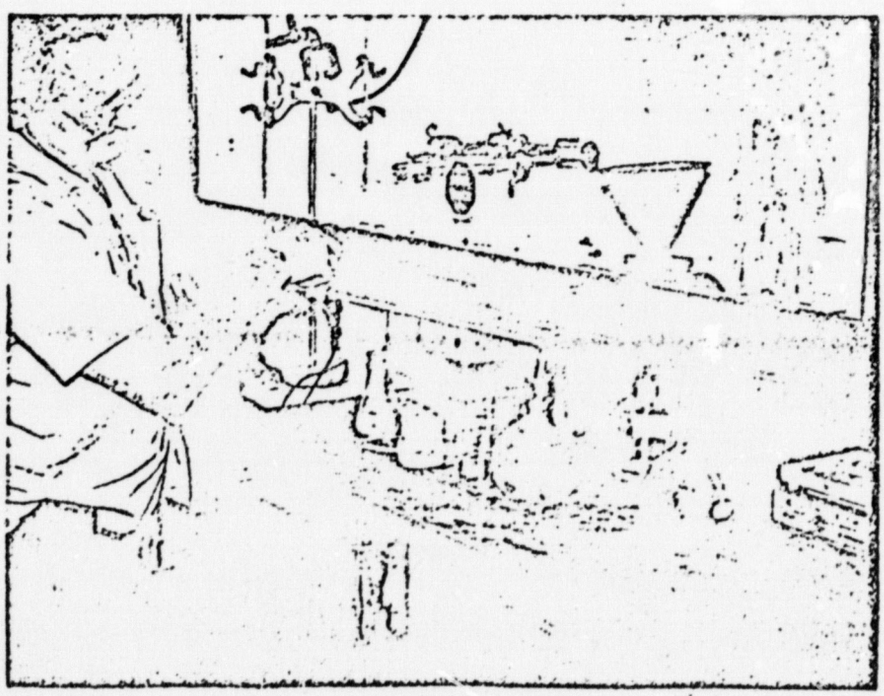
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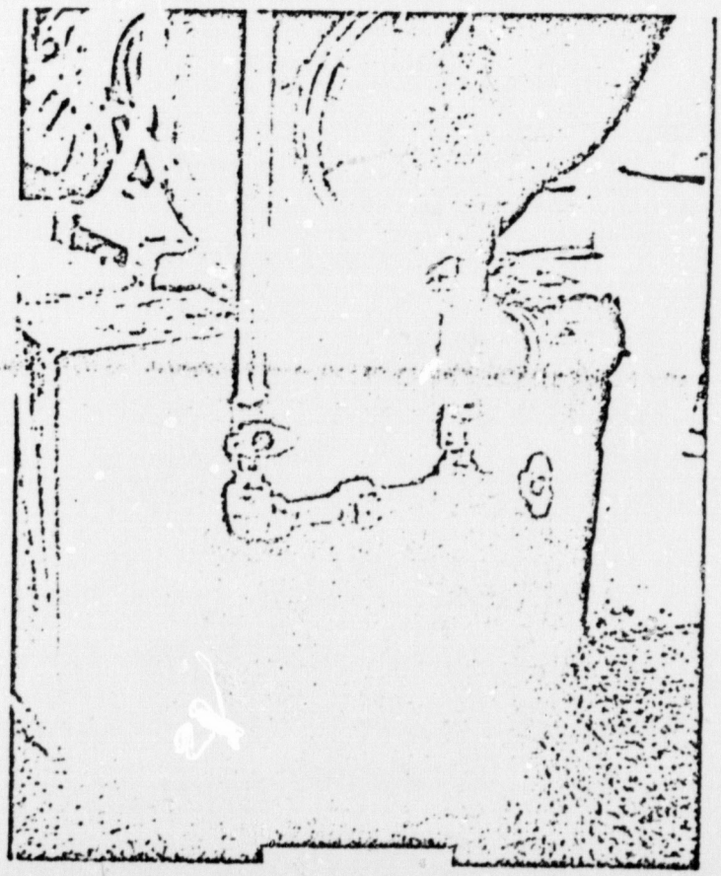
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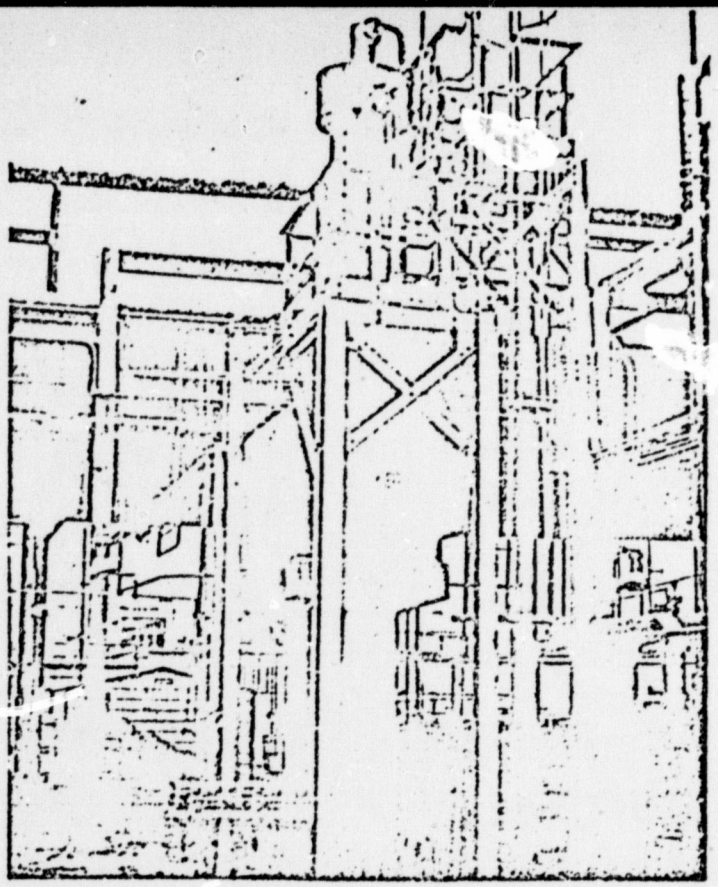
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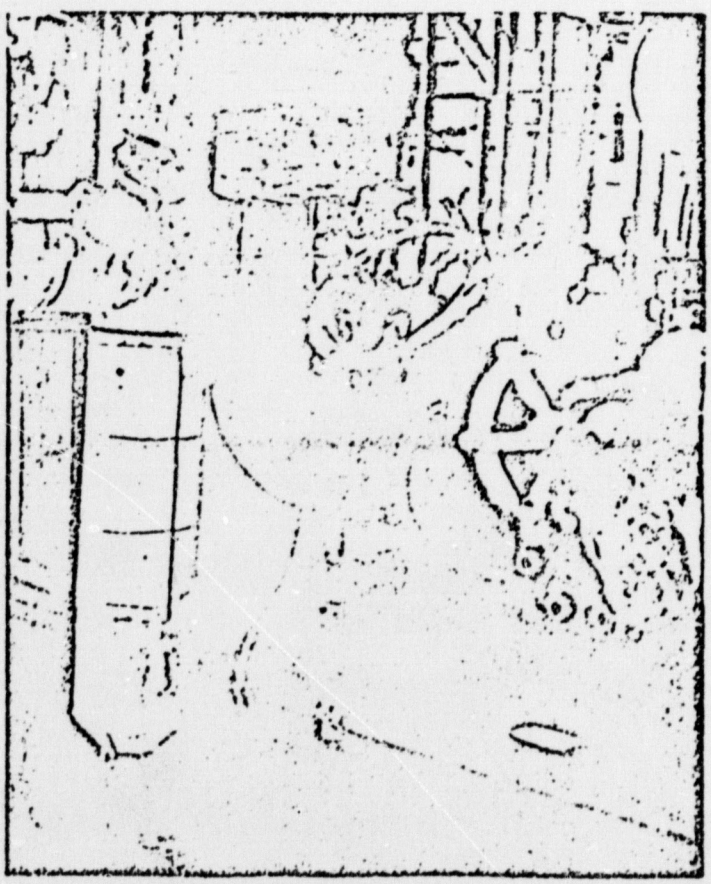
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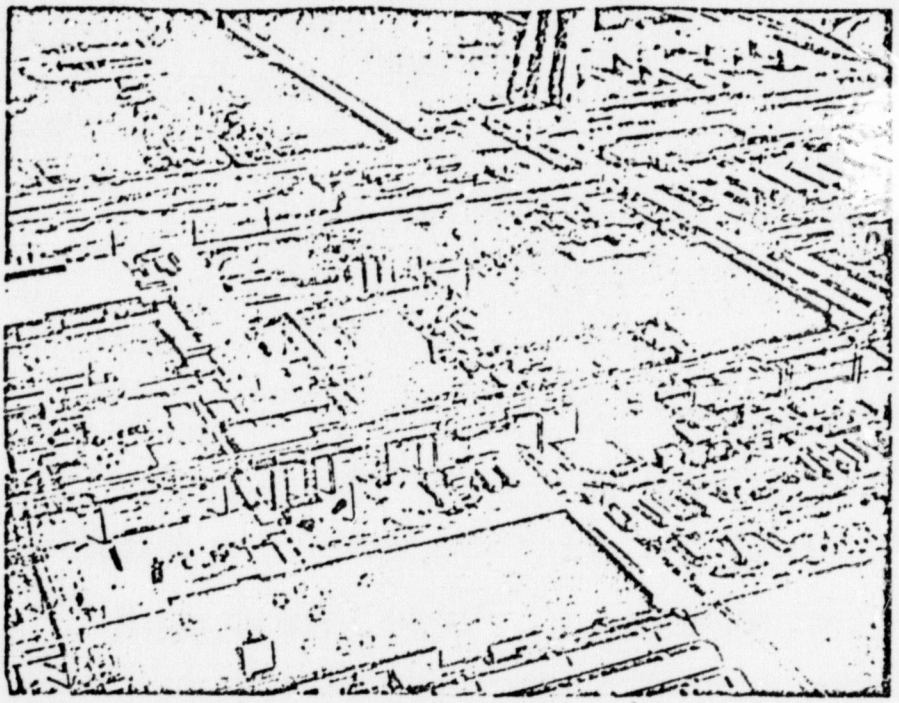
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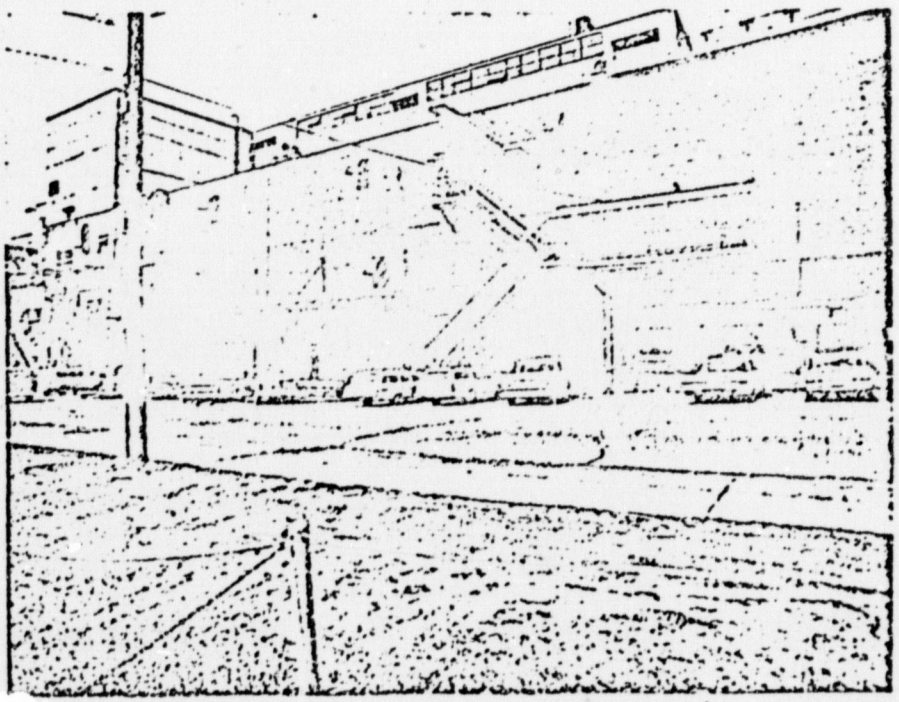
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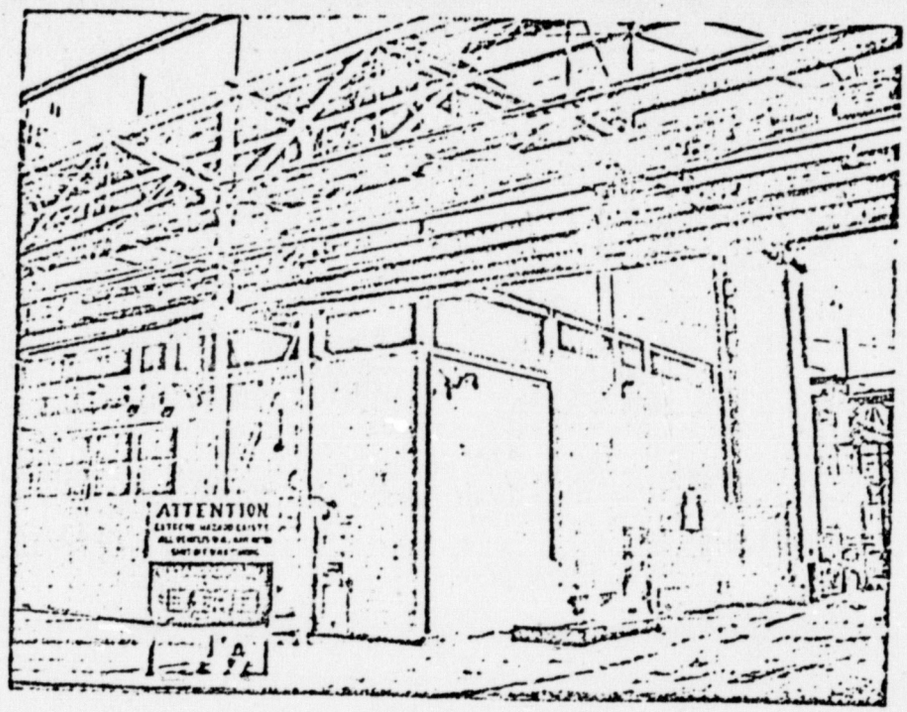
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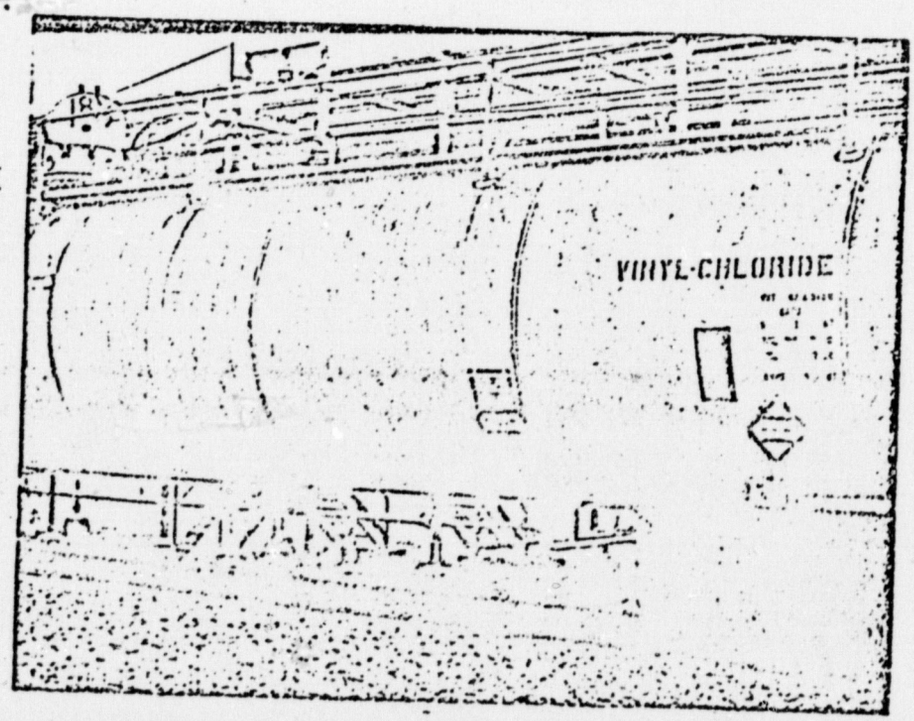
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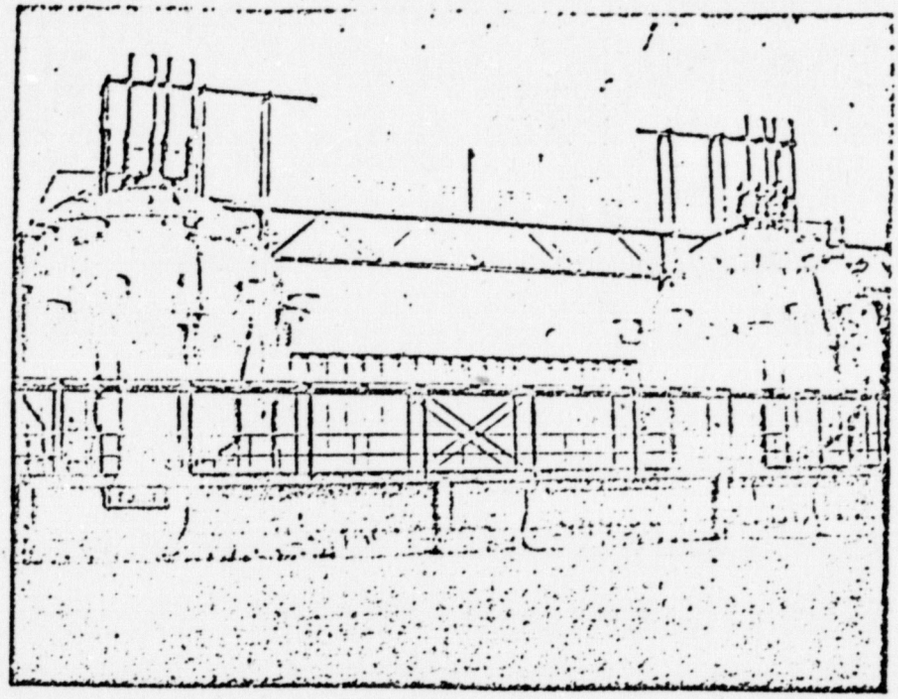
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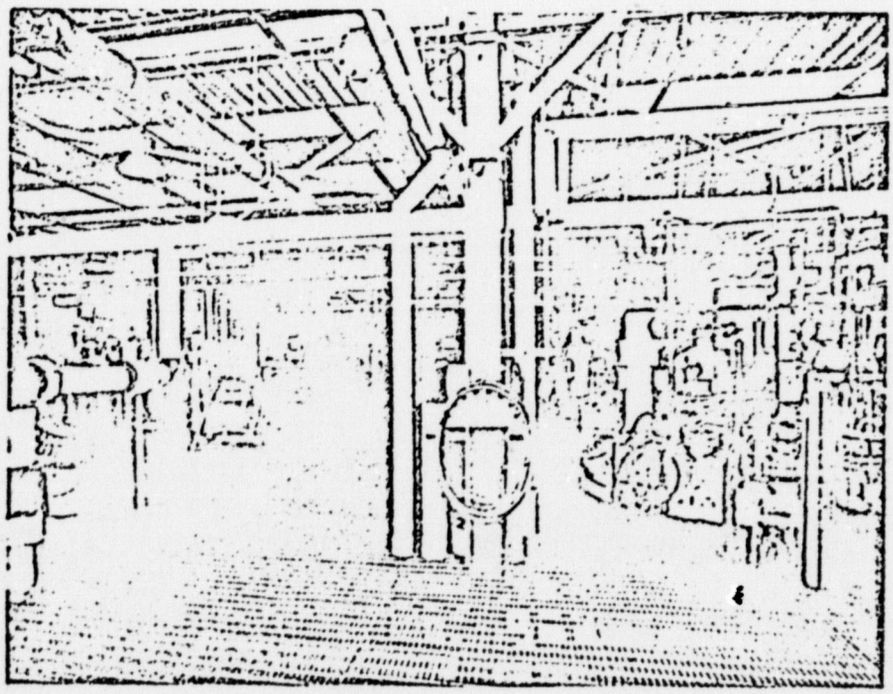
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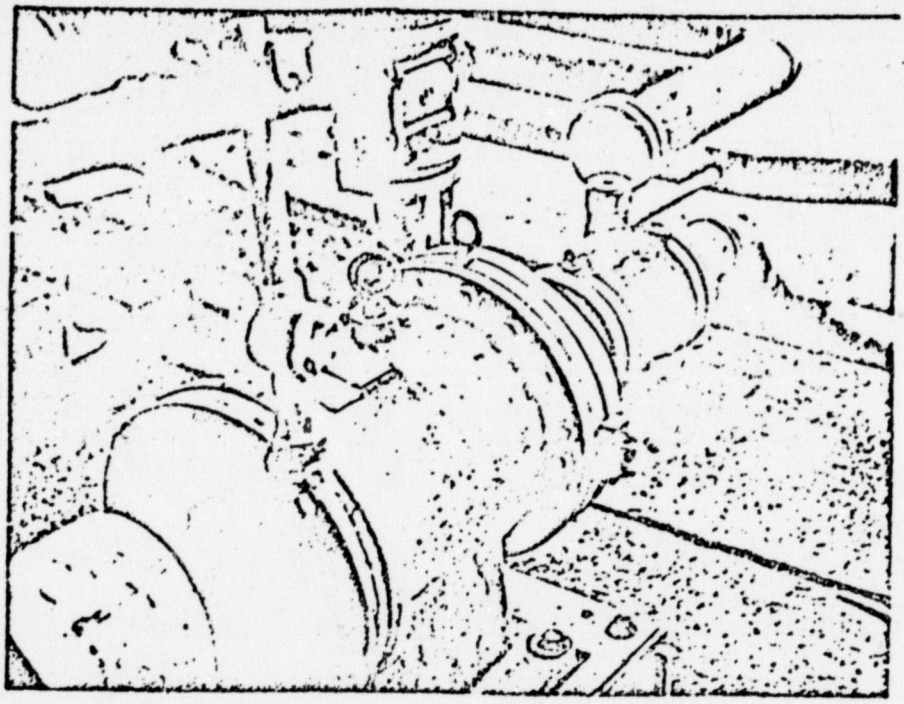
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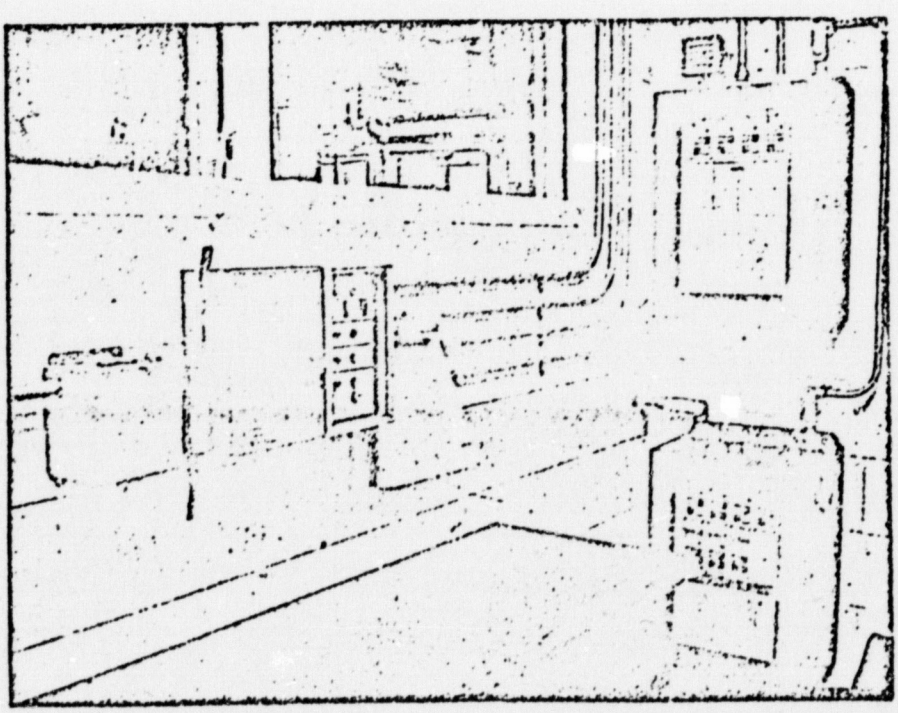
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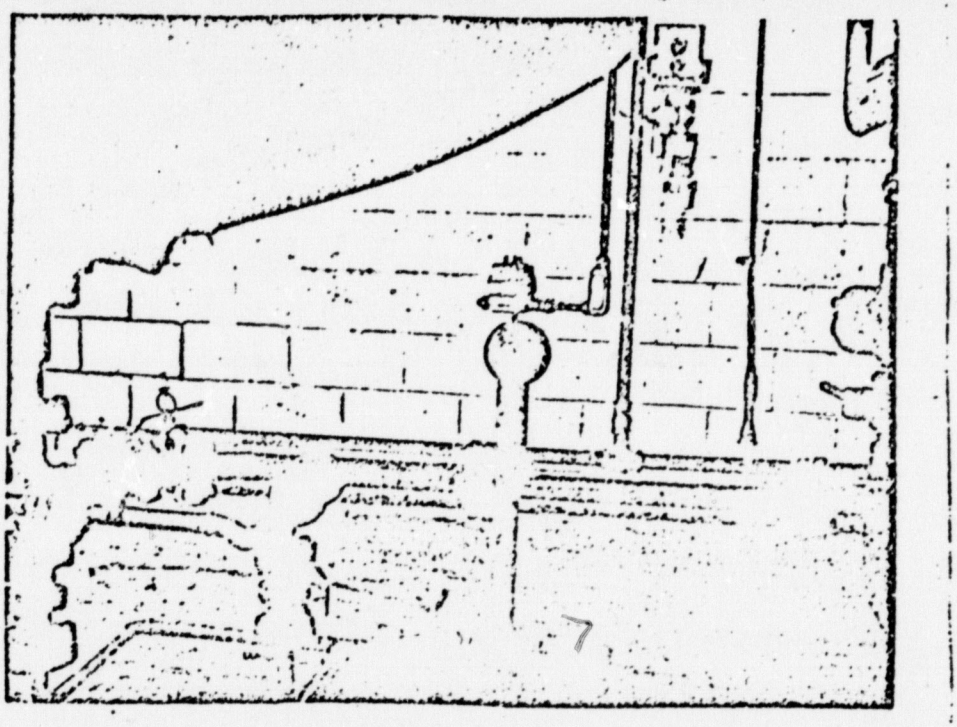
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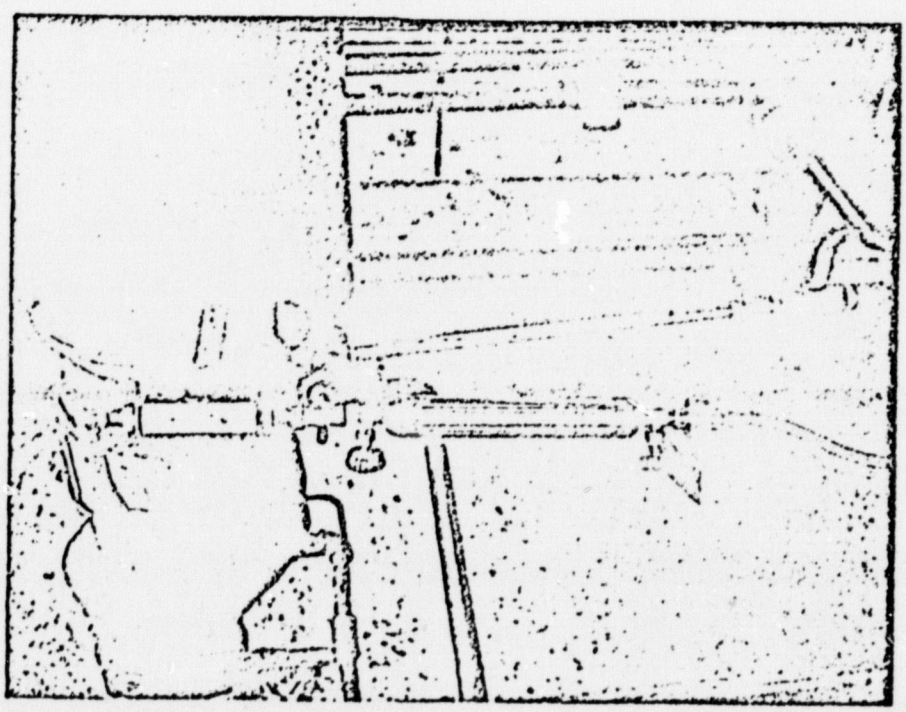
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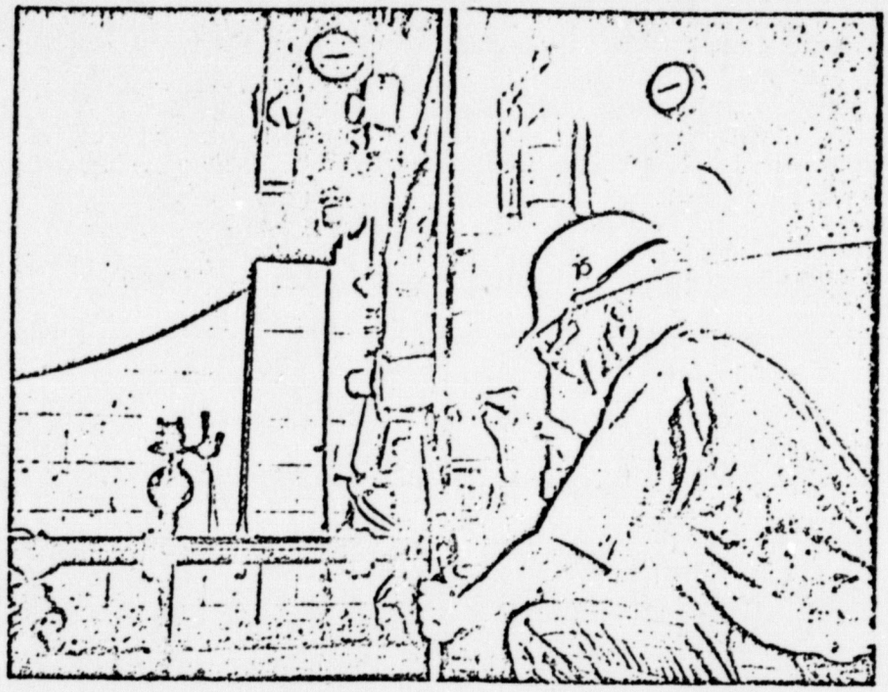
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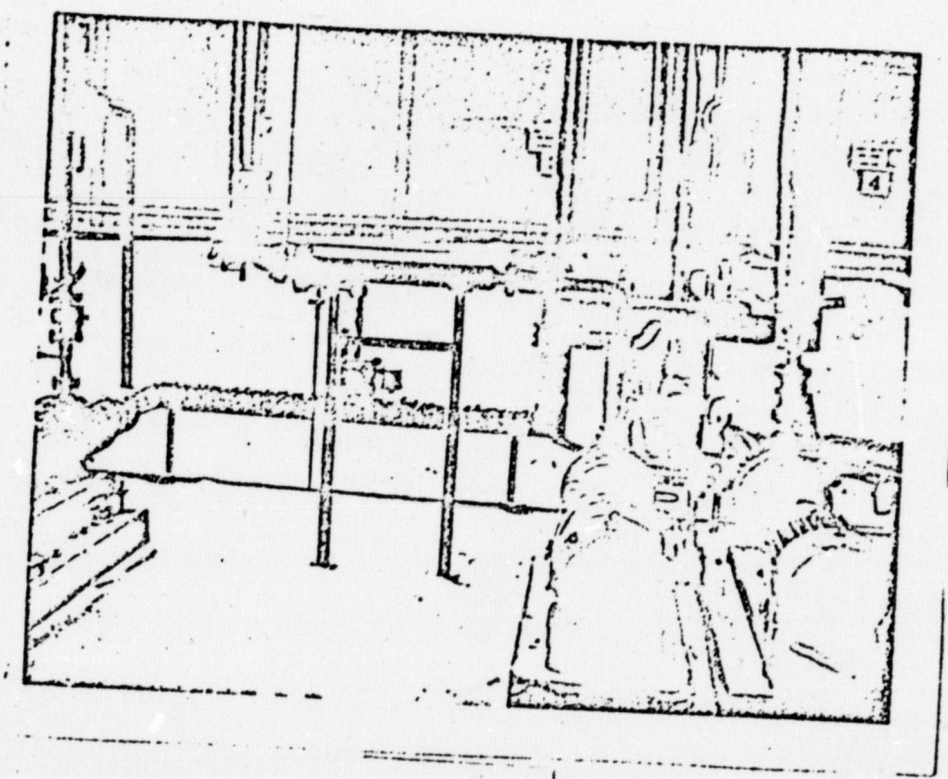
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Slide 33



Slide 34



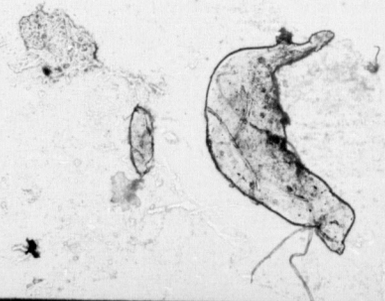
Slide 35

WE WANT NOW TO RETURN TO MR. OELFKE WHO WILL DISCUSS THE POSITIVE AND NEGATIVE CHARACTERISTICS OF VARIOUS TYPES OF RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING.

KARL

PROTECTIVE EQUIPMENT

K. H. Oelfke
The Dow Chemical Company
Freeport, Texas



Slide 1.

Respiratory Equipment:

Respiratory equipment is required for certain routine operations as well as for maintenance and emergency operations. Several types of respiratory equipment have been used in the past. The most convenient and portable pieces of respiratory equipment are the cartridge and canister types. The most convenient of these is the nose-mouth cartridge respirator.

Slide 2. It is easy to don, but does interfere with certain types of eye protection such as chemical goggles. Its small size and light weight make it idea to carry at all times for escape should an emergency arise.

Slide 3. One of these canisters of approximately 100cc was tested for breakthrough to 1ppm at a flow of 30L per minute. It lasted 15 minutes.

Slide 4. Next we have the full face canister type respirator. The improvements that we have here over the nose-mouth type is that the larger canister provides longer protection and eye protection is an integral part of the mask. Wearing of a hard hat becomes more difficult with this type mask.

Slide 5. An Acme canister of apprixmately 300cc was tested at 1000 ppm vinyl chloride to determine breakthrough to 1ppm. At 23 minutes, the effluent measured 1.1ppm.

Slide 6. The full face canister type with a chest mounted canister offers still longer protection.

Slide 7. On the same basis as the previous two data slides, we have a 1ppm breakthrough after 167 minutes.
All of these data were obtained at 30 liter/minute in contrast to the 53 liter/minute mentioned in Mr. Hyatt's presentation.

Slide 8. Of interest here is data that were obtained to determine the effect of a different carbon PCB 12x30 obtained from Calgon Corporation when compared to that normally supplied in an AOR-31 cartridge. You will note that the breakthrough to 1ppm from an inlet concentration of 50ppm VCM for the PCB carbon was at 75 minutes, while the AOR-31 was at 35 minutes. These tests were conducted at 32 liter/minute.
While we agree with NIOSH that leakage can occur through certain of the cartridge respirators at high concentrations of vinyl chloride and that certain of the masks don't fit all faces, we feel that cartridge or canister respirators can serve a very useful purpose in protecting employees.

Slide 9. In the air supplied respiratory equipment, we have the continuous flow air supplied hood. We have called it an "acid hood" in the past. It offers very good head spill protection, but this unit has major disadvantages such as bulkiness, vision restriction, and lack of movement of the head.

Slide 10. The continuous flow air supplied half mask offers some good advantages, but here again interferes with full eye protection.

Slide 11. The continuous air flow full face mask is probably the best of the air supplied breathing apparatus.
With the last three types of continuous air flow respiratory equipment, mobility becomes difficult because of the length of air hose that must be "trailed". For specific jobs where mobility is not a problem, such as single tank car loading, this does not pose a great problem.

Slide 12. Where mobility is a necessity, such as in an outdoor vinyl chloride monomer plant, the self-contained breathing apparatus has been used. The major disadvantage here is that the air supply is limited. In the pressure demand mode, these units are nominally rated for 15 and 30 minutes. This one for 15 minutes. Actually, we have found that with activity of

the wearer, these times are more like 10 and 20 minutes. You will please note that these times were in the pressure demand mode, not continuous flow.

Slide 13. For specific jobs, such as breaking or entering on maintenance jobs, portable breathing air cylinders can be used to provide longer respiratory protection. One of these cylinders would provide approximately 2 hours of air when demand is at 53 liters/minute.

What is really needed in a vinyl chloride manufacturing or use plant? This depends upon the potential exposure. Where monitoring shows no excessive vinyl chloride no respiratory equipment should be required. When breaking and entering such as tank car loading and unloading, where transfer lines can be purged of vinyl chloride and monitoring has shown that no excessive exposure will result, then none should be used. Where breaking and entering and potential exposure is not known, such as on maintenance work, then air supplied masks should be used until danger of exposure has passed.

Slide 14.

Canister Gas Masks

1. Can provide protection.
2. Are portable.
3. Should be allowed.

Air Supplied Masks

1. Have limited areas.
2. Should be used in specific jobs.

Self-Contained Masks

1. Are bulky and heavy 33 pounds.
2. Limited air supply.
3. Are essential in case of emergency.

In other words, the requirements for respiratory equipment should be dictated by the problems at hand in the workplace. The wearing of many kinds of respiratory equi[illegible]under certain conditions can create a safety hazard.

Slide 15.

Protective Clothing

Protective clothing as presently defined by the standard "means clothing protective against vinyl chloride."

Slide 16. The requirement can only be fully met with a full impervious pressurized suit with a self-contained breathing air mask. The expelled air tends to keep the suit with a slight positive pressure. The use of this type suit and protective clothing should be limited to emergency situations, not as general practice. In one test, made on June 14, 1974,

at our Texas Division, the following data was obtained. Body temperature of subject before test 98.4°F.

Slide 17. After 5 minutes sitting, skin temperature measured 100.9°F.

Slide 18. 5 minutes of slow walking.

Slide 19. Body temperature was 102.6°F and skin temperature was 101.8°F.

The ambient dry bulb temperature was 85°F.

In addition to this unacceptable heat stress, this suit tends to be a safety hazard in itself because of limited visibility and bulkiness. Hearing is difficult. Communication with others is almost impossible.

I have only seen this type suit used twice. Once was during a large hydrochloric acid spill and the other during an attempt to blind off an aqueous ammonia line.

In conclusion, I would like to say, let the situation establish the need for and the type of protective equipment required.

RESPIRATORY PROTECTION

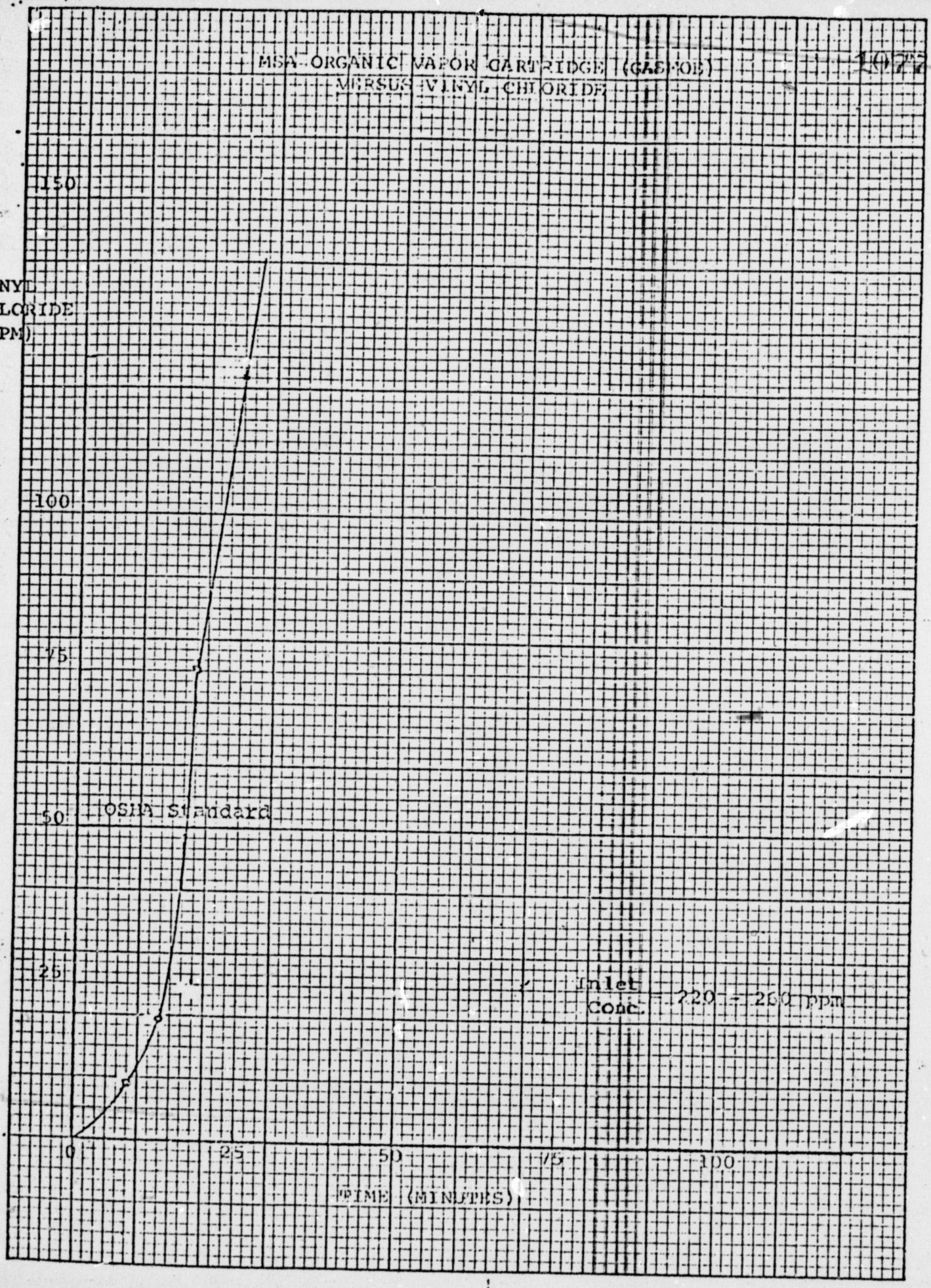
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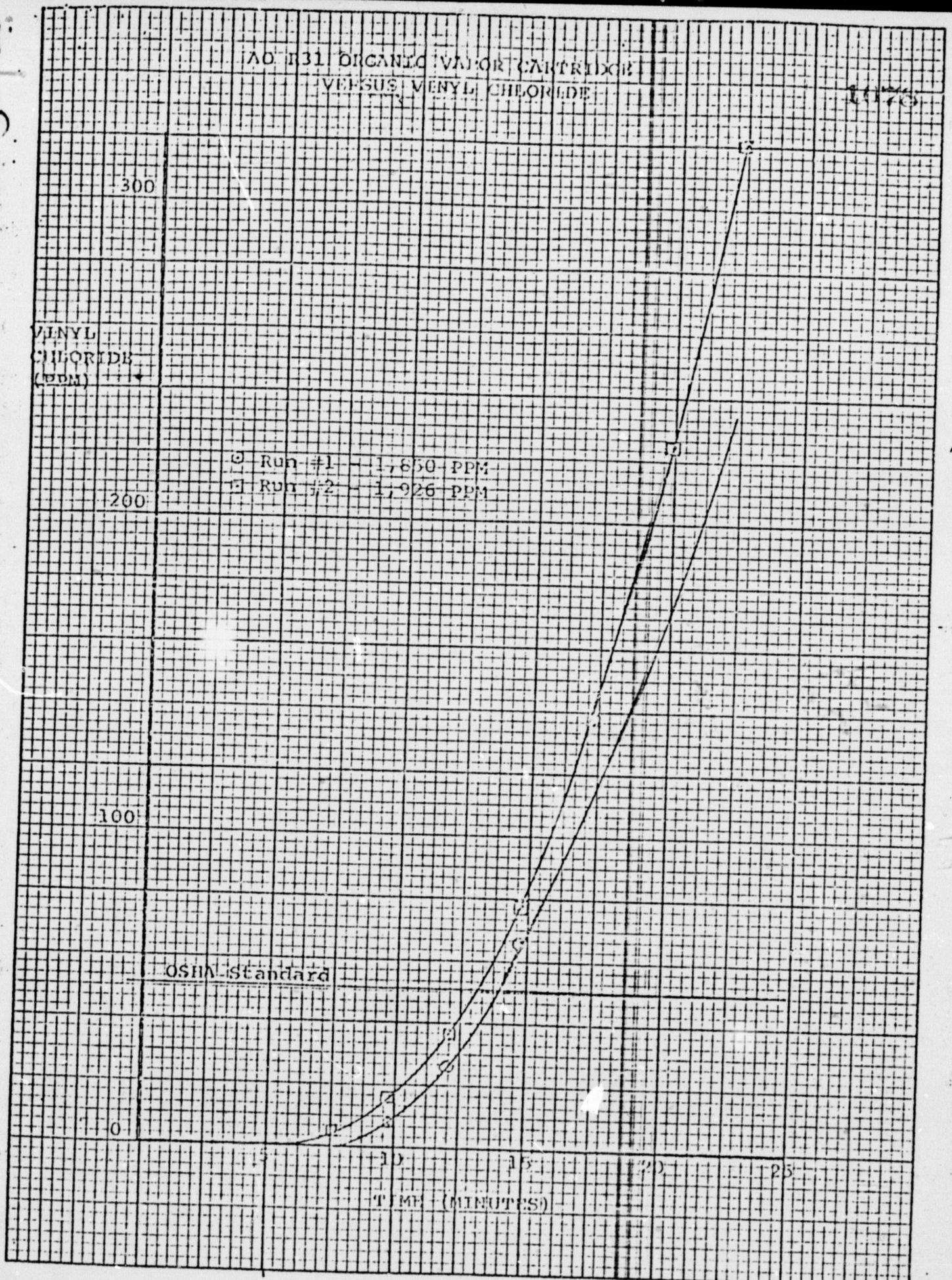
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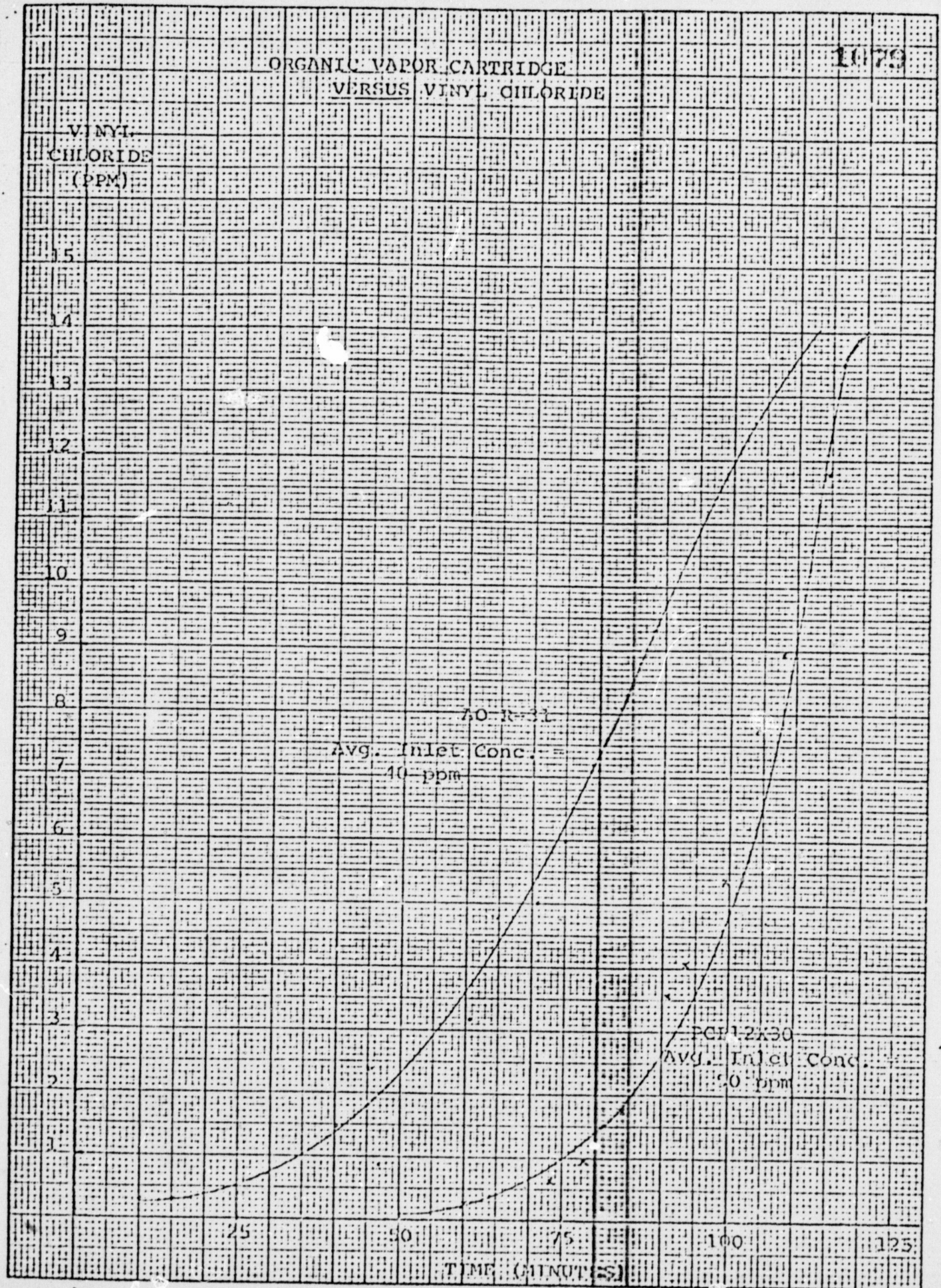
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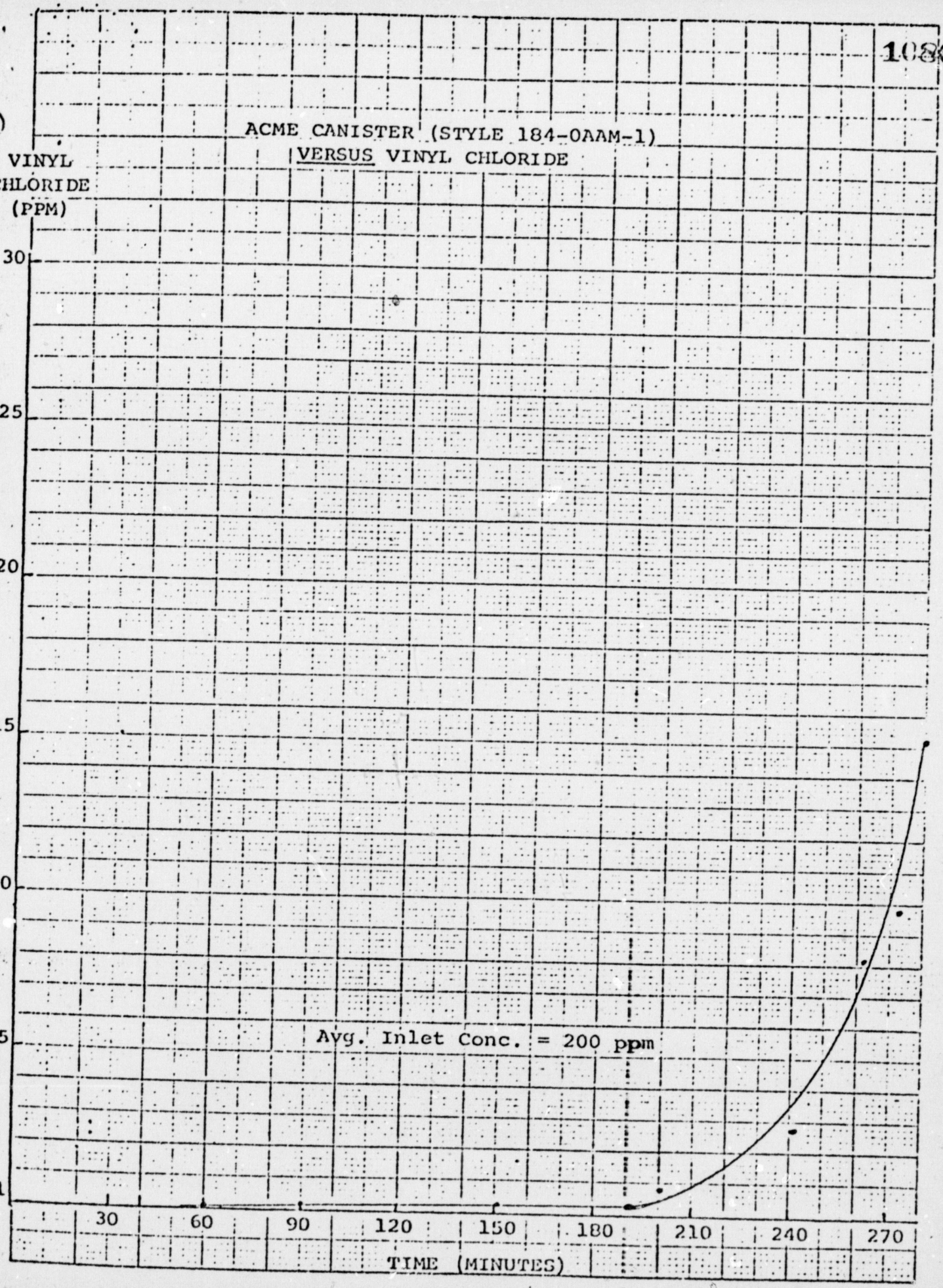

MSA ORGANIC VAPOR CARTRIDGE (GMC-OE)
VERSUS VINYL CHLORIDE
VINYL CHLORIDE (PPM)
150
100
75
50
25
0
OSHA Standard
Inlet Conc. = 220 - 260 ppm
25
50
75
100
TIME (MINUTES)

Slide 4


AO 331 ORGANIC VAPOR CARTRIDGE
VERSUS VENYL CHLORIDE
300
VENYL
CHLORIDE
(PPM)
200
100
0
Run #1 - 1,650 PPM
Run #2 - 1,926 PPM
OSHA Standard
5
10
15
20
25
TIME (MINUTES)

Slide 5


ORGANIC VAPOR CARTRIDGE
VERSUS VINYL CHLORIDE
VINYL CHLORIDE (PPM)
15
14
13
12
11
10
9
8
7
6
5
4
3
2
1
70 lpm
Avg. Inlet Conc. =
40 ppm
PCM 12x30
Avg. Inlet Conc. =
20 ppm
25
50
75
100
125
TIME (MINUTES)


ACME CANISTER (STYLE 184-0AAM-1)
VERSUS VINYL CHLORIDE
VINYL CHLORIDE (PPM)
30
25
20
15
10
5
1
Avg. Inlet Conc. = 200 ppm
30
60
90
120
150
180
210
240
270
TIME (MINUTES)

Slide 7

ACME
(Cat.# 502-1C)

- 1000 PPM_v Vinyl Chloride
- 30 Liters/Minute Flow
- 15 Minutes — 0.68 PPM_v

Slide 8

ACME
(Cat.# 272-CL-L)

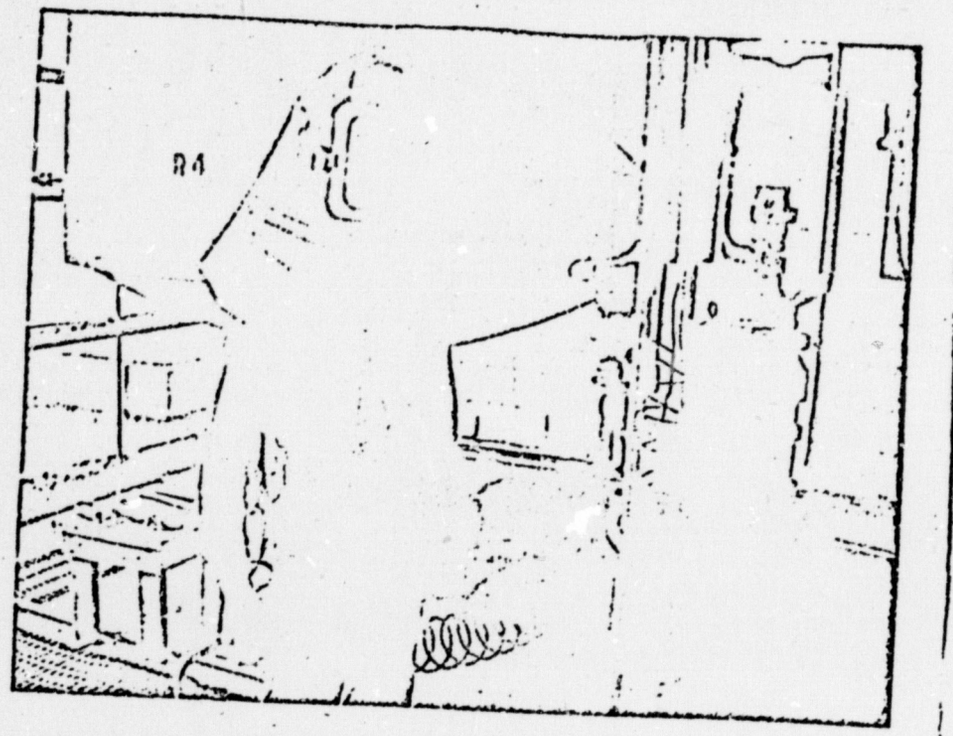
- 1000 PPM_v Vinyl Chloride
- 30 Liters/Minute Flow
- 22 Minutes — 0.72 PPM_v

Slide 9

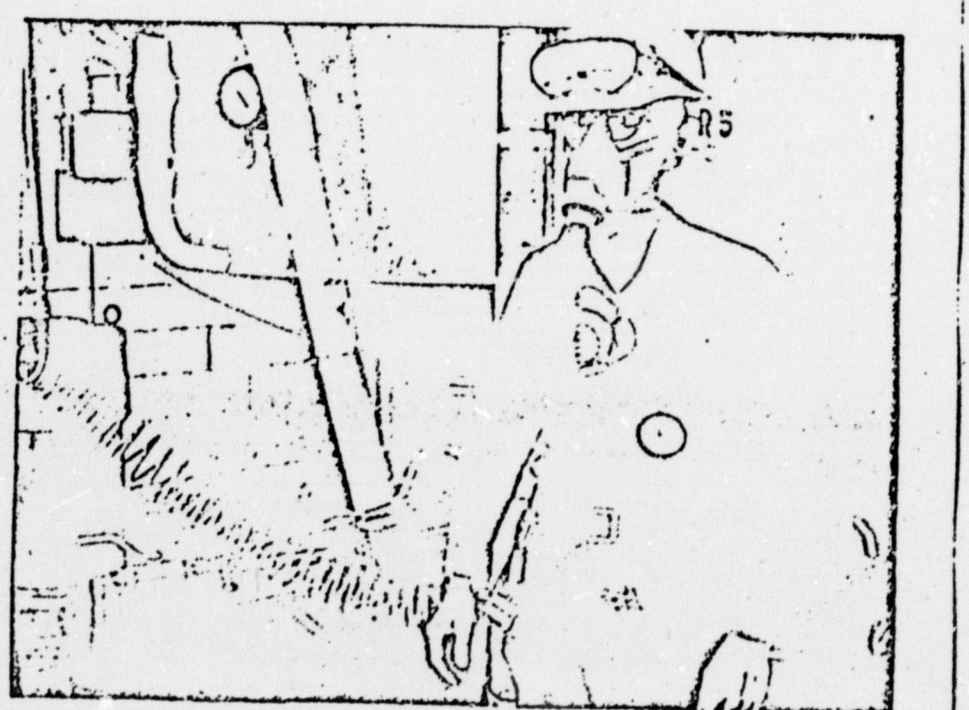
ACME
(Cat.# 184-OVAG-L)

- 1000 PPM_v Vinyl Chloride
- 30 Liters/Minute Flow
- 167 Minutes — 0.89 PPM_v

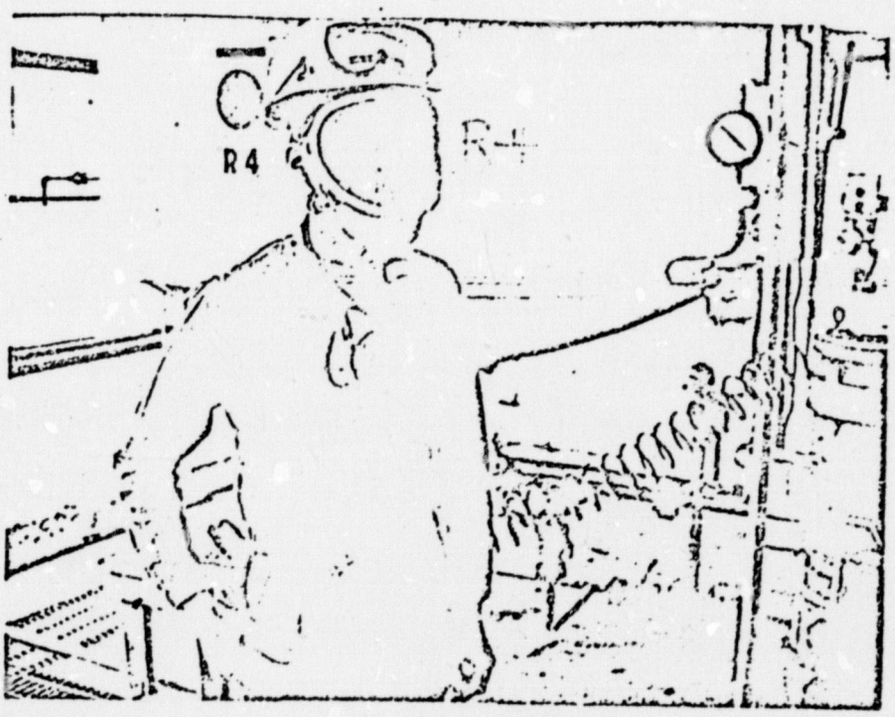
Slide 10



Slide 11



Slide 12



Slide 13

RESPIRATORY EQUIPMENT

CANISTER GAS MASKS
- Can Provide Protection
- Are Portable
- Should Be Allowed

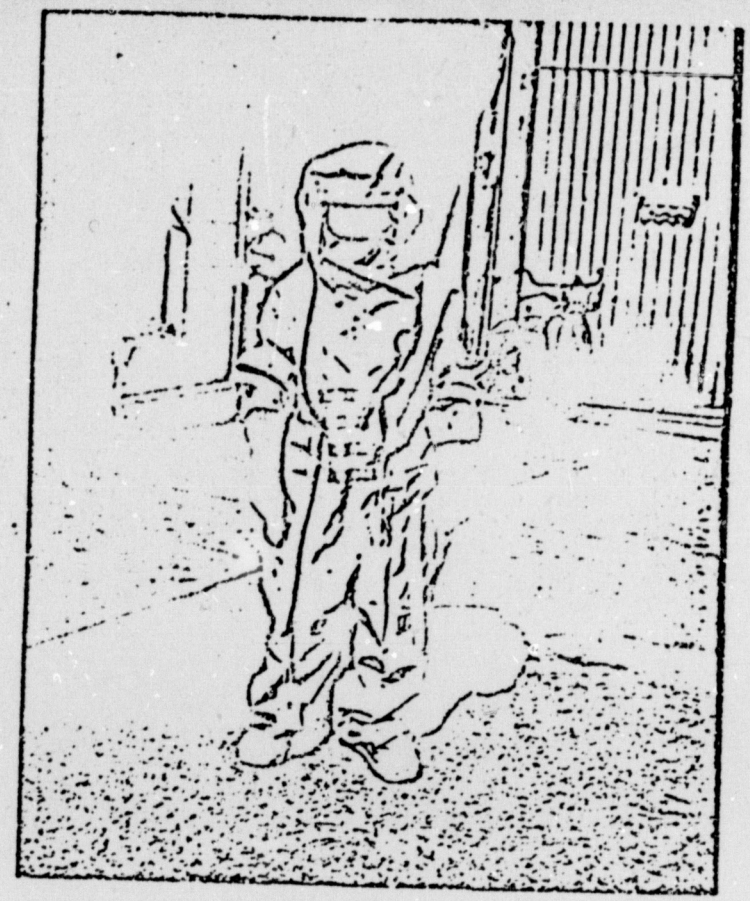
AIR SUPPLIED MASKS
- Limited Areas
- Should Be Used

SELF CONTAINED MASKS
- Bulky And Heavy
- Limited Air Supply
- Emergency Use

Slide 14

PROTECTIVE CLOTHING

Slide 15



Slide 16



Slide 17



Slide 18

IMPERVIOUS SUIT
DRY BULB TEMP 85°F

Time, Min	Body Temp	Skin Temp
0	98.4°F	94.4°F
5	—	100.8°F
10	102.6°F	101.8°F

Slide 19



Slide 20

WE SHALL NOW TURN TO OUR MEDICAL STAFF FOR A REPORT OF THEIR OBSERVATIONS. FIRST, I SHALL CALL ON DR. RALPH COOK WHO IS IN CHARGE OF THE MIDLAND DIVISION'S HEALTH INVENTORY PROGRAM. DR. COOK WILL DESCRIBE THIS MEDICAL SURVEILLANCE PROGRAM AND GIVE THE RESULTS OF HIS OBSERVATIONS.

DR. COOK

Peak exposure data in Table VII -- (next slide) -- show that the laboratory technician does receive a part of his exposure during analysis of the product. The loading technicians exposures are within permissable levels while disconnecting tank cars, but we are still using fresh air masks for this operation. The low peak exposure data for the repair technician are attributable to the thorough purging job that was done prior to opening the equipment for maintenance. See, this value is one ppm on a 10-minute sample basis.

An area monitoring system is on order for this facility and equipment delivery is promised in mid-July. The system will be similar to that at Monomer Plant No. 2 both in cycle time and sensitivity.

In our copolymer facility Dow has had a comprehensive vinyl chloride surveillance program since 1950.

(Next slide.)

This is a summary of the TWA exposures for the ten-year period 1950-59. The product produced is a copolymer of vinyl and vinylidene chloride, and, the air contaminant is a mixture of these two compounds rather than pure vinyl chloride. In the emissions, the relative ratios are 85 parts vinyl chloride and 15 parts vinylidene chloride. During this period, the vapors were absorbed on silica gel and a total chloride determination made in the laborator. The total chloride calculated as vinyl chloride are shown on this slide. Note that TWA's as high as 385 ppm and excursions as high as 4,000 ppm

were experienced.

(Next slide.)

Since 1960, a continuous area monitoring system has been in operation. This is a non-specific analyzer based on the combustion-conductivity approach. These data are a summary of the TWA exposures for 1960-63. The drier operator had the highest TWA/ 85 ppm and the excursions were now down to 500 ppm compared to the 4,000 ppm experienced in the 1950's. The TWA's were calculated based on the predesignated time the operator normally spent in each area.

Continuous air analyses are still performed using the combustion-conductivity analyzer. The output from the analyzer is now computerized and a typical daily summary report is shown in the next slide. We are not trying to point out numbers here, but merely the approach that we have for handling the data. (Next slide.)

There are 18 sample point locations; the sample time per point is approximately 1/2 minute. The data are summarized for each eight hour shift. The information includes the number of samples taken at each location, the average of all samples, the maximum concentration at each location and the time at wh which the maximum occurred. These data are then time-weighted, based on the predesignated time the operator normally spends in each area, to produce a TWA exposure distribution.

(Next slide.)

Again, the data are presented for each shift. The

ing 31

report shows the percent of the work day the employee spends at various exposure levels:/ Note the 591 polymer operator on 0.5 ppm; 5-10 ppm, and so forth. the day shift where 81 percent of his time was in the 0-5 ppm level and 3 percent was in the 25-50 ppm range for an eight-hour average of 5.1 ppm. The analyzer is set to alarm at 25 ppm; from the analyzer employees can determine the location of the problem. Appropriate respiratory protection is worn in the area while the problem is being corrected.

(Next slide.)

This is a summary of average exposures for February through May 1974 for the four job classifications shown on the previous daily report. These data show that level can vary by a factor of three from month to month. Note also the shift to shift random variation.

We have discussed the calculated TWA's from area monitoring. Now let's look at some recent personnel monitoring data. Same operator classification.

(Next slide.)

These data support the day-to-day variations observed by area monitoring.

(Next slide.)

The packager operator has generally low exposure but still has/had day-to-day variations.

Using charcoal absorption tubes short term area samples were collected to identify these operations which

required.

JUDGE MYATT: Thank you, gentlemen.

Mr. Kline.

MR. KLINE: I will start off by asking whether you have a specific recommendation as to appropriate levels.

MR. OELFKE: I beg your pardon, Mr. Kline?

MR. KLINE: Do you have any recommendations as to what the levels in the final standard, if there is going to be one, should be?

MR. OELFKE: We have concurrence with the SPI presentation.

MR. KLINE: What is the basis of that conclusion?

MR. OELFKE: The rule of reason and technical feasibility.

MR. KLINE: Could you be more specific on that, please?

MR. OELFKE: I have tried to demonstrate the complexity of the production plant, what we have done in the past, and the problems that we face in the future, to get down to OSHA's proposed permanent standard of one part per million, at no detectability.

MR. KLINE: When you project in the future as to what levels you might be able to reach, could you tell us what the processes are and what your starting off point is in reaching those conclusions?

MR. OELFKE: It would be very difficult, Mr. Kline, to put that into words.

I think judgment has a lot to do with it. We are really just now starting to get into the knowledge of where our potential exposures are as a result of our monitoring.

I think we have been able to reduce our exposures considerably by taking care of the larger exposure points. We can knock off the top pretty fast.

But when we get down to the bottom, then it becomes more and more difficult. Right now, I think it is technically not feasible.

MR. KLINE: How have you concluded that, for example, a TWA average of 25 ppm throughout the industry would be feasible?

MR. OELFKE: I don't think that we have suggested that 25 parts throughout the industry would be feasible.

MR. KLINE: You mean you are recommending a standard that is not feasible?

MR. OELFKE: No.

I think that the recommendation was by the SPI 10 ppm/TWA for a monomer plant, and 25 ppm/TWA for a polymerization plant. I think that's right. I could be mistaken.

MR. KLINE: That is more or less correct, I think, yes.

I am not sure on what basis you conclude that 25 parts per million TWA should be the standard as of October 1974.

MR. OELFKE: Mr. Kline, I haven't really concluded that myself personally.

MR. KLINE: Would you tell us what you have concluded then?

MR. OELFKE: Well, I have concluded that it is technically infeasible to get to a no detectable limit of vinyl chloride monomer by October 5, 1974. I think that we have to have a rule of reason, whether our technological developments, to be able to reduce our exposures, our planned reduction of exposures.

MR. KLINE: I take it, then, from your comments that you think that you could get lower than five ppm by October '74, TWA?

MR. OELFKE: On the monomer plants, we certainly can get --

MR. KLINE. Excuse me. I am just talking about the PVA plants, just for now.

MR. OELFKE: I have no expertise in the range of PVA plants as such.

MR. KLINE: Okay.

Let's turn to the monomer plants.

What level would you recommend for the standard?

MR. OELFKE: Mr. Kline, I have stated that we were in agreement with the SPI on 10 ppm/TWA as of October 5, 1974.

Then I am also in agreement with the October 5, 1975,

I believe it is, getting to 5 ppm/TWA for monomer plants.

MR. KLINE: Could you indicate for us, please, how you arrived at the 10 ppm in 1974 and how you arrived at the 5 ppm in 1977, I think, or 1976, whatever it is?

MR. OELKE: I don't remember what the date is. I think it is a consensus of opinions what can be done by October 5, 1974.

It is a consensus of opinion. I can only speak for my own plant.

We are going to be working towards a 5 ppm/TWA as soon as -- certainly as soon as the standard -- if the SPI recommendation is accepted as the standard -- we will be working, starting today, to get to a 5 ppm/TWA by 1975, October.

We would fully expect -- we have got to get to a much lower level than that for consistent 5 ppm/TWA.

MR. KLINE: If the level were, in the future, going to be set at lower than 5 ppm, would you go about arriving at that level differently than you would if it was going to be set at 5 ppm/TWA?

MR. OELKE: I am sorry. Would you repeat that question?

MR. KLINE: Sure.

If the level, for example, were going to be set at one ppm, say, two or three years from now, would you go about reaching that level differently than you would if the level w

set at 5 ppm?

MR. OELFKE: I doubt it very seriously.

We have to find out where our problem areas are. And we have attempted to do so at the present time.

MR. KLINE: I am trying to figure out how you can project what level will result from the institution of new engineering controls -- how you could say "I think we could reach 5 but we can't reach 1, 2, 3 or 4."

MR. OELFKE: I am afraid I can't answer that specific question, Mr. Kline.

MR. KLINE: Let's talk about leaks in monomer plants for a moment.

Other than what you have indicated in your testimony, are there any steps that you have taken to reduce the exposure caused by leaks?

MR. OELFKE: Preventive maintenance, I think, is the biggest step that we have tried to institute in our monomer plants.

MR. KLINE: Could you tell us, generally, what type of preventive maintenance you found that does reduce leaks?

MR. OELFKE: Well, to start off, you would have to find them first.

Let's assume that we have a leak. We do have a problem, as I indicated there, on our reciprocating compressors without packing purges. The packing is suitable and does reduce the

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vinyl chloride leakage, but we are having to continually monitor and maintain that packing in the reciprocating compressors.

We do have a paint program -- particularly up in Monomer Plant No. 1 is located on the Gulf Coast where we have a high rusting of our equipment as a result of the salt air. We do have a painting program about once every three years where we completely repaint the plant, a third of the plant per year basis.

MR. KLINE: Does that help act as a sealer for leaks?

MR. OELFKE: Pardon?

MR. KLINE: Does the paint help act as a sealer for the leaks?

MR. OELFKE: No.

The paint helps to keep the leaks from occurring, from exterior corrosion.

MR. KLINE: I see.

MR. OELFKE: I can't think of any other illustrations, Mr. Kline.

MR. KLINE: Do you know to what extent the level of exposure is reduced by the use of centrifugal force with respect to leaks as opposed to the other methods that you utilize?

MR. OELFKE: No, I really have no definitive data as to the amount that it is reduced.

MR. KLINE: Do you have an estimate that you could give us today?

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MR. OELFKE: No, I'm afraid I do not.

MR. KLINE: Do you think that something you could supply for us in a posthearing comment?

MR. OELFKE: I think we have attempted to measure the amount of vinyl chloride that we do -- leakage that we do experience from our reciprocating compressors.

An estimate, I am sure, could be given. We can do that.

MR. KLINE: Now, I take it that the reason why you have not used the centrifugal force in the other plants is primarily an economic one.

Is that a fair assumption?

MR. OELFKE: That's correct.

MR. KLINE: Do you know approximately what something like that would cost?

MR. OELFKE: We estimate that the replacement of the five non-packing compressors in our Monomer Plant No. 1 would cost $500,000. And we have at least a shell of the centrifugal compressor that we think that we can use in this application.

MR. KLINE: Now, in the time weighted average figures that you have given us for the monomer of the PVA plants, do you have any measurements as to the excursions, the high levels of exposure, or do you merely have the time weighted average?

MR. OELFKE: I don't have any data with me today on the excursions. I don't know whether Roger has it with him

today or not.

MR. KLINE: Well --

MR. OELFKE: We have been taking time weighted averages since, I think, 1971, as was testified to. I don't know to what degree or to what elevation the time weighted averages were.

MR. KLINE: Would you have just single excursions in your records?

For example, if somebody had a time weighted average exposure, say, of 10 ppm, it is conceivable, is it not, that at some point or another, the person was exposed to perhaps 100 ppm -- at least in theory?

Would your records indicate that type of excursion?

MR. OELFKE: No, they would not, because we have been using the carbon absorption, which does not give the excursion level.

What we have done in the past -- and I don't want to add too much -- but what we have done in monitoring is taken the time weighted average and then calculated it as ten-minute peak exposure.

In other words, we take all of the vinyl chloride that came off the absorption tube through the eight-hour sampling and calculated the peak that would have occurred if all of the vinyl chloride had occurred at ten minutes.

As a result of this, because of the Clean Air Act, I guess, somebody referred to it as 1910.93, the time weighted

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averages that were referred to -- this is the reason why we have been doing that.

MR. KLINE: Incidentally, if you could supply in a posthearing comment as to each of the distinct processes -- No. 1, identify the type of process; No. 2, the amount and type of VCM and/or PVA produced or used in '73; and the approximate numbers in each of the job categories that you have indicated to us today, we would appreciate that.

Is that type of information available, sir?

MR. OELFKE: Do you have a list of your requests that you could go over one more time?

MR. KLINE: Sure.

For each of the distinct processes, if you could identify the type of process --

MR. OELFKE: You are talking about Monomer Plant No. 1, Monomer Plant No. 2, and Monomer Plant No. 3?

MR. KLINE: And also with respect to PVA.

MR. OELFKE: The coal polymerization plant.

MR. KLINE: Excuse me. Okay.

And if you could identify the amount and type of VCM and PVC produced or used in 1973, and the approximate numbers in each of the job classifications that you have.

MR. OELFKE: In other words, you want our employee census?

MR. KLINE: Yes. Just statistics rather than individual

names or anything like that.

If you could do that, we would really appreciate it.

MR. OELFKE: I think we can. I will have to check further with our management on that -- amounts of production.

MR. KLINE: We would appreciate that.

MR. OELFKE: Certainly.

MR. KLINE: Let's talk about the loading. That seems to be a problem in the monomer plant particularly.

MR. OELFKE: Yes.

MR. KLINE: Does an employee stay at loading for a full eight hours every hours, or seven and a half hours, whatever it is, or is it more or less intermittent?

MR. OELFKE: Well, I think that we have some that load tank cars on a fairly continuous basis at our Texas Division.

The number of tank cars is not as great as those that are at our Oyster Creek Division or our Louisiana Division.

The loading of vinyl chloride at the Texas Division is in conjunction with loading other products.

So, today, he might load two tank cars of vinyl chloride and tank cars of other products. While the Oyster Creek Division would be loading considerable numbers of vinyl chloride tank cars.

At our Oyster Creek Division, they load vinyl chloride in addition to other products.

So, as far as tank car loading, yes, the people out

there at the tank car loading facilities, but we don't always load vinyl chloride tank cars at each facility -- I mean except at the Oyster Creek Division.

MR. KLINE: Now, the level of exposure, is that an intermittent type thing, or is that pretty much continuous?

MR. OELFKE: I think it would be an intermittent type thing, because he is not normally out on the tank car itself. He is normally off where he can observe the loading of the tank cars, the connection and disconnection of the vent lines.

MR. KLINE: If you can answer this question -- it's a very broad question -- is there sn approximate length of time that it takes to unload the cars for vinyl chloride?

MR. OELFKE: Yes, but I'm afraid on the unloading of the tank car, it is different than the loading. I don't know what length of time it takes to unload. But the man is not specifically up on the tank all during the unloading operations.

MR. KLINE: So, then, I take it that you would not know how many times you would have to come up to the tank car and actually be exposed?

MR. OELFKE: On the unloading, we unload directly from the tank car into spheres, so that he doesn't have to come up on the tank car, for instance, and unload a little bit, and get back up and block the valves, for instance, and then return say, two hours later or a day later, because of insufficient storage.

Is that what you have reference to?

MR. KLINE: No.

I thought that the major exposure from unloading and loading was the short-lived fog that comes out.

MR. OELFKE: No.

That is just one of our problems. And I was just trying to tell you what we are trying to do to eliminate that fog.

The major exposure has been in the past a combination of the fog from the gauge tube, and the disconnection of the tank car loading lines, loading and vent lines. We pretty much eliminated the tank car loading and unloading line as an exposure point.

We have not eliminated it all. But our next step is to continue with our nitrogen purging of our unloading and vent lines, and the replacement of that innage tube that does spew vinyl chloride to the atmosphere, replacing it completely.

MR. KLINE: Do you have an idea when that will be replaced?

MR. OELFKE: We estimate that it will be done -- that all of our tank cars, all of our vinyl chloride tank cars will have this innage tube replaced with the magnetic type gauge by the end of 1975.

MR. KLINE: Have they been actually ordered already, and is that a delivery date that has been indicated to you?

MR. OELFKE: I can't specifically attest to that, but

it is still a reasonable type of delivery. That is an estimate on my part.

We have gauges, to the best of my knowledge, on order, and I do not know of the delivery times on the gauges.

We have a program to try to replace at least two of the magnetic gauges per week as the tank cars come back in and we have the gauges.

MR. KLINE: Is there exposure when there is onstream analysis?

Is there employee exposure there?

MR. OELFKE: No.

MR. KLINE: Let's talk about pumps for a moment, if we could, and similar type areas which appear to be some problem.

What's the problem with the pump in terms of exposure?

And what steps have you taken on trying to cut down on exposure from pumps?

MR. OELFKE: Well, we use mechanicals fills on our pumps -- you may or may not be familiar with mechanical fill on rotating equipment.

The standard packing that we think of for years gone by has been compressed asbestos or carbon packing, which is completely unsatisfactory for chlorinated hydrocarbon such as vinyl chloride, because of the leakage that must be there to lubricate the packing, to keep it from burning up.

We have used -- we do use mechanical seals, even though, through some of our monitoring, we have found that the mechanical seals, even though they don't look like they are leaking, are emitting some small amounts of vinyl chloride.

We have estimated it in the neighborhood of one pound per pump per day. That's not very much, but it is still there.

MR. KLINE: Could you translate that into parts per million?

MR. OELFKE: No, I am sorry, I can't.

MR. KLINE: What about the reboilers and filters? What are the problems with them?

MR. OELFKE: Well, in the maintenance or the cleaning of the reboiler, the reboiler must be drained, and then most of ours are vertical tube reboilers with the vinyl chloride on the tube side with steam or some heating medium on the shell side.

As a result of the heating that takes place in the reboilers, we do get some polymerization, and polymerization does not allow the heat transfer coefficient to be high enough to maintain good reboil on the column.

We do try to reduce all of the liquid contents of the reboiler back to the process prior to for maintenance.

But, as in some of the polymerization plants, I heard testimony yesterday, there is a potential hangup of the vinyl chloride in the scale inside the reboiler that could be released, and that is a potential exposure point.

MR. KLINE: Directing your attention to the polymerization plant, you have indicated that you are testing the sealless or canned pumps.

MR. OELFKE: That is correct.

MR. KLINE: Do they appear to be working?

MR. OELFKE: This one does.

My experience in the past on canned pumps in chlorinating hydrocarbon service has been entirely unsatisfactory.

MR. KLINE: This pump that you have now, is that a licensed matter, or could you make the test results available to us?

MR. OELFKE: The pump that we have now is a pump that is available on the open market. I don't know what its name is.

MR. KLINE: You say --

MR. OELFKE: It is in intermittent service, Mr. Kline, and this is different than the continuous process pump that would be experienced in a vinyl chloride manufacturing plant.

MR. KLINE: Could you make those test results that you have indicated available to us?

MR. OELFKE: I don't have test results on the canned pumps that I experienced.

All I know is that I paid about three times what a standard pump, centrifugal pump, for the canned pumps, for one installation.

You understand, I could have put in three of the

standard pumps for one of the canned pumps. And this was on a column overhead, or the distillate of a column, and it was entirely satisfactory.

We could not keep the pumps running. We changed them out.

Now, this is not a vinyl chloride, but I can supply that, the name of that pump that we are testing there.

MR. KLINE: Okay.

We would appreciate that.

Now, you have indicated that the new polymerization areas are highly automated.

Could you give us an indication of what type of automation has been involved?

MR. OELFKE: Highly automated, computerized -- and this is what we consider proprietary information. I hesitated to bring that up.

But we have used extensive use of computers in our coal polymerization plant.

MR. KLINE: Could you give us a range of about how often it becomes necessary to open up lines in equipment for service?

MR. OELFKE: In the co-polymerization plant?

MR. KLINE: Yes, sir.

MR. OELFKE: This is not by my own knowledge. This is hearsay that I would be giving.

I understand that we open the polymerization kettles after each polymerization. In some of our older kettles, we must open the manhole for washout.

In our newest polymerization kettles, we have a small eight-inch opening where we wash the inside of the kettle. This is done on each polymerization batch.

MR. KLINE: I would like to direct your attention now to the respirators.

MR. OELFKE: Yes, sir.

MR. KLINE: What is the absorbent used in the AOR-31?

MR. OELFKE: I do not know.

It's carbon.

MR. KLINE: It is a form of carbon?

MR. OELFKE: Yes.

MR. KLINE: Could you make available to us on your testing of the canister type respirators the underlying data for that?

MR. OELFKE: You mean our methods of analysis, or our methodology -- I don't quite follow what your question is.

MR. KLINE: The various readings as they appear.

MR. OELFKE: Yes.

You mean like after one minute --

MR. KLINE: Yes.

MR. OELFKE: Yes, I think we can supply that, yes.

MR. KLINE: We would appreciate that.

MR. KLINE: Now, have your employees been wearing these cartridge canisters?

MR. OELFKE: As required by the emergency temporary standards, some of our employees have been wearing air supplied respirators. They have not been wearing the canister respirators, as a matter of course.

They do carry canister respirators with them in the plant for use in a case of an emergency escape -- in case of an emergency.

MR. KLINE: So I take it, then, the results that you have gotten with respect to the canisters have been experimental rather than actual use in the plant?

MR. OELFKE: The data that I reported on the canister cartridge was strictly experimental. But it did refer to 1,000 ppm vinyl chloride.

MR. KLINE: At what level would you recommend the cartridge canisters with carbon in them as a filter be used?

MR. OELFKE: I have no knowledge -- I have no opinion. I am merely presenting the data that we required as a result of some of our testing of the canisters.

MR. KLINE: Leaving aside the question of technical feasibility right now, in terms of protecting employees, at what level would you recommend the use of respirators?

MR. OELFKE: I am not in a position to recommend a level at which they would use respirators.

All I really said was that they should be allowed, particularly for escape, in case of a -- a catastrophe. I call it a catastrophe, but I will call it a spill or an emergency condition.

MR. KLINE: Would you recommend that they be used on sort of a continuing basis by employees?

MR. OELFKE: No, I would not.

MR. KLINE: Let's talk about the exposure of the people that do the analysis work for you.

MR. OELFKE: Okay.

MR. KLINE: What measures, other than the hood, have you instituted in order to reduce the exposure?

MR. OELFKE: Well, throughout the years, we have tried to improve our analytical techniques in working with our customers to reduce the amount of analysis that's required. That is essentially what we have done.

MR. KLINE: Now, the analysis -- the people who do the analysis work, do they do it on a full eight-hour day?

MR. OELFKE: Normally, they do it -- the laboratory people work on analytical work for an eight-hour period of time, yes.

MR. KLINE: And is that analytical work with vinyl chloride?

MR. OELFKE: Not all the time, no, sir.

MR. KLINE: Now, do you know what time an average

employee would spend doing analytical work with vinyl chloride?

MR. OELFKE: I can only assume. I would assume -- I would prefer not to assume anything.

MR. KLINE: I appreciate that.

Do you think you could supply that in a posthearing comment?

MR. OELFKE: I think we could.

MR. KLINE: Okay.

Thank you very much.

MR. KUCHENBECKER: Mr. Oelfke, I have two questions.

Do the leaks that you have identified so far account for the total amount of VC emitted to the work placeatmosphere?

MR. OELFKE: I don't know yet.

MR. KUCHENBECKER: You haven't made any readings as far as the total VC that is in the work place?

MR. OELFKE: Yes, I have.

But it is very difficult -- if I had a room like this and I could measure the amount of VC in the room and change the air on a periodic basis, and still can measure the VC, then I could estimate how much leakage we had.

Where I have an outdoor plant, I am going around to each of the potential leak point sites, like valves, gaskets, compressors, filters, this type of thing.

MR. KUCHENBECKER: Well, I was wondering as far as, perhaps, the percentage of fugitive losses, that you can't nail

them down -- that you could seal the leaks and things you have located so far -- how low could you go at that point?

MR. OELFKE: I do not have any estimate of that.

MR. KUCHENBECKER: Could you make any recommendations, as far as the protective equipment, for entering vessels, reactor vessels?

MR. OELFKE: I have no data on vinyl chloride absorption.

MR. KUCHENBECKER: Have you any recommendations as far as respirators to be worn when somebody climbs into a reactor vessel, what type of protective clothing, if any, they should wear?

MR. OELFKE: I have no expertise in that area.

MR. KUCHENBECKER: Does anyone on the panel up there care to direct themselves to that question?

Okay. Thank you.

MR. KLINE: Thank you very much, sir.

JUDGE MYATT: Before we take questions from the floor, we will take a five-minute break.

(Short recess.)

JUDGE MYATT: Ladies and gentlemen, they have taken the gavel away.

If you prolong this much longer, they might take your mikes away. So, let us get going.

I am going to ask those of you who come up from the floor to ask questions to identify you, although we probably know who you are. The reporters are constantly switching and they have moved themselves down to the floor where we can't give them the names.

So, repeat your name, please, and your organization before you address the questions to the witnesses.

Are there any questions from the floor?

Yes, Mr. Samuels.

MR. SAMUELS: Sheldon Samuels, Industrial Union Department.

First, let me say that I think that your presentation VK, is a pacesetter for the industry. It is excellent. And because, Mr. Olefka, you are going to be going, I would like to address all my questions to you and perhaps save others when others testify.

First, do you think there should be unnecessary exposure to vinyl chloride?

In other words, I noticed you were fighting, if I can use that word, to reduce exposures in your plants in as many operations as possible. And I assume that is because you don't

think that there should be any unnecessary exposure of vinyl chloride.

MR. OLEFKE: It has been our position in the years gone by that we reduce our exposures to all chlorinated hydrocarbons to the lowest possible limits.

MR. SAMUELS: Do you think that the rest of the industry ought to do at least as well as you do in these operations?

MR. OLEFKE: I cannot testify to the rest of the industry. I am speaking of the philosophy.

MR. SAMUELS: I don't mean what they can do but what they should do.

Do you think that they ought to be making the same effort?

MR. OLEFKE: I think unnecessary exposure to any foreign material is a bad thing.

MR. SAMUELS: Many of the operations, if I understood the tables -- and forgive me if I couldn't read them all clearly -- but many of the operations are already below the SPI recommendations, isn't that so?

MR. OLEFKE: Yes, it is.

MR. SAMUELS: Do you feel that there should be an exposure up to the SPI recommendations even though it is not necessary?

MR. OLEFKE: We do not feel that the ten parts per

million as suggested by the SPI has a license to operate at ten parts per million on a TWA.

In fact, we feel like it should be considerably lower than that on an average in order to insure that you will be below the ten parts TWA in a VCMA.

MR. SAMUELS: Thank you.

Now, it seems to me, looking at the table, that at least some of the operations were even below one part per million.

Is that right?

MR. OLEFKE: I believe that is correct, yes, sir.

MR. SAMUELS: So that indicates that for some operations the proposal could be met as your plan has described exists right now for some operations on an operation by operation basis?

MR. OLEFKE: Let the data speak for itself, Mr. Samuels.

MR. SAMUELS: Do you think it is possible to further automate or otherwise redesign your process?

Not simply add supplemental controls and minor equipment changes to bring down the whole process of making vinyl chloride?

Have you been able to address -- I realize it has been a short period of time. This thing has occurred only since January. You have not been able to address yourself to

this.

But have you thought about redesigning the entire process, integral controls?

MR. OLEFKE: Yes, we have thought about it.

MR. SAMUELS: And --

MR. OLEFKE: Certainly.

MR. SAMUELS: Is this something that the project that you have initiated, have you asked design engineers to look at the construction of brand new facilities that might completely come within the proposed target?

MR. OLEFKE: I think, as I testified, Mr. Samuels, we don't have a technology at the present time to reach the level that has been proposed by OSHA in a permanent standard for everyone involved in vinyl chloride manufacturing.

MR. SAMUELS: But have you tried to develop the technology?

MR. OLEFKE: Yes, we have.

MR. SAMUELS: And you have asked plant design engineers to see if they could develop the technology to meet the proposed standards?

MR. OLEFKE: I have considerable number of engineers on my staff and they are working toward that, yes.

MR. SAMUELS: They are working toward the proposal?

MR. OLEFKE: Yes.

MR. SAMUELS: On the problem of tank carry cars, the

pictures were excellent, of course, and when a -- in a loading operation, when the worker is topside, in one picture it showed the tank was open.

At that point, is it feasible for him to wear a respirator?

MR. OLEFKE: No, the picture did not clearly display that he had on a respirator, but he did have on a respirator.

I put in two slides in the tank car operation. One specifically showed that he had on a respirator. The other one was a little bit hidden. I did not point that out, but he did have on a respirator.

MR. SAMUELS: I couldn't see.

Was it a cannister type?

MR. OLEFKE: No.

It was air supply, full face.

MR. SAMUELS: Full face respirator.

So it is feasible to provide a respirator for that operation and it was one of the two operations which seemed to be, if I may use the term, not in a derogatory sense, the dirtiest operation, the most exposed operation.

The laboratory technicians and the tank car operators seemed to have the highest exposure?

MR. OLEFKE: That is correct, yes.

MR. SAMUELS: And for the tank car operators, at the point of highest exposure, respirators you demonstrate to be

feasible?

MR. OLEFKE: I think that it is required. I am not absolutely certain, but I think that that is required by the emergency temporary standards at the present time.

MR. SAMUELS: And you have been operating under that, and have you had any difficulties?

MR. OLEFKE: We have not had any difficulty from the safety standpoint, Mr. Samuels, except our operator told me he isn't going to wear that damn thing until we figured out a way so that he wasn't exposed.

I mean, that was the kind of the way he told it.

MR. SAMUELS: I understand the resistance to wearing it.

But, otherwise --

MR. OLEFKE: He is wearing it, yes.

MR. SAMUELS: Okay. That is different.

Now, for the lab techs, I understood you to say that there really -- that the lab techs don't constantly analyze vinyl chloride.

MR. OLEFKE: That is correct.

MR. SAMUELS: So that it would only be for short periods of time during which, if one were required, he would have to wear one.

If the hood itself weren't adequate -- I thought I saw a picture of the hood, is that right?

MR. OLEFKE: Yes, sir.

MR. SAMUELS: And you felt, and your measurements indicated that the hood was not adequate?

MR. OLEFKE: No, I am not exactly sure that that was all of the exposure, Mr. Samuels.

I was trying to illustrate that we were making job studies of his work in trying to pick out exact points where he was exposed. And as we worked on those points, we -- as we discovered those points, we could do something about them.

MR. SAMUELS: I see.

You feel that the lab techs could be fully protected then?

MR. OLEFKE: Eventually we want to reduce the exposure for all of our people, yes.

MR. SAMUELS: And you would probably agree with Professor Corn when it comes to hood design. You could do 100 percent?

MR. OLEFKE: I don't know Professor Corn. I do not know what he said.

MR. SAMUELS: All right.

I saw two other slides on the respirators, and it had some data on it, and one number was 1,000 parts per million.

MR. OLEFKE: Yes.

MR. SAMUELS: Now, was that the amount, the concentration of the vinyl chloride that you measured the breakthrough

in?

That is to say, you were theoretically trying to find out what the breakthrough time would be at a concentration of 1,000 parts per million, is that right?

MR. OLEFKE: We were trying to determine the period of time that it would take the outlet air on the respirator to reach one part per million when exposed to an inlet of 1,000 parts per million.

MR. SAMUELS: Right. Okay.

Now, what would the breakthrough times be at normal exposures?

In your tables I didn't see any exposures of 1,000 parts per million, thank God.

MR. OLEFKE: I really don't know. We had one slide, as you remember, where we were comparing MOR 31 cannister with PVC 12, about 30 at 50 parts per million.

I do not know what the breakthrough would be at our normal low level of exposure.

MR. SAMUELS: But it would certainly be much longer, wouldn't it, in your judgment, than the breakthrough times at 1,000 ppm?

MR. OLEFKE: It would certainly be, in my judgment, a longer period of time, yes.

MR. SAMUELS: There was one figure that seemed to me that the breakthrough time was two hours or more at 1,000 ppm.

Is that right.

MR. OLEFKE: 167 minutes, as I recall.

MR. SAMUELS: And so, therefore, it is quite possible that at least for four-hour periods, assuming that workers get breaks at lunch and so forth, a single cannister might suffice for many of these highly exposed operations?

MR. OLEFKE: I am afraid that is a judgment that I cannot make, Mr. Samuels.

MR. SAMUELS: Okay.

Thank you very much.

MR. OLEFKE: You are welcome.

JUDGE MYATT: Yes, sir?

MR. COTTINE: Bertram Robert Cottine, Health Research Group.

I have one procedural request.

Will photographic positive prints of your slides be submitted for the record aside from the tables which, of course, do appear?

JUDGE MYATT: They are contained in the presentations.

MR. COTTINE: They are?

Fine. Thank you very much.

With your skill and experience, Mr. Olefke, did you on any one of your qualifications adopt, participate in the preparation of the SPI reccmmended standards?

MR. OLEFKE: I did not participate in the SPI.

MR. COTTINE: Did someone at Dow though participate with your engineering and practical experience?

MR. OLEFKE: Someone from Dow participated, but I can't testify to his --

MR. COTTINE: Fine.

I will direct it to someone else on the panel.

Okay.

Did you or anyone, again with your qualifications, at Dow participate in the revision of the MCA material safety date sheet in 1972?

MR. OLEFKE: I am not aware of this participation.

MR. COTTINE: Now, would you be the person on the panel familiar with any complaints or enforcement, inspections that have taken place at Dow?

MR. OLEFKE: I am familiar with some, yes.

MR. COTTINE: Have there been any such inspections for vinyl chloride exposure by any governmental agency?

MR. OLEFKE: Yes, there have been.

MR. COTTINE: And could you identify the agencies that have inspected the plants?

MR. OLEFKE: OSHA has inspected all three of our vinyl monomer plants.

I think that the EPA has inspected our Louisiana division plants.

MR. COTTINE: Are you familiar with the safety -- I

am sorry, the sample data sheet as a result of the monitoring done at that time?

MR. OLEFKE: I have received and have not any of the OSHA sampling data sheets.

MR. COTTINE: But they were prepared and sent to you?

MR. OLEFKE: I have not seen them.

MR. COTTINE: You haven't seen them but they have been received?

MR. OLEFKE: No.

I don't know that they are going to send us any data sheet as such. I don't know that it is required.

I don't know have, and I should have the ones for the Texas Division certainly.

MR. COTTINE: Once again, I will direct the inquiry to the Secretary.

Could those be submitted for the record, please, with respect to the three plants?

MR. KLINE: To the extent that they are available, we will.

MR. COTTINE: Fine.

Now, with respect to the EPA inspection, have you been provided with any data with respect to their monitoring your plants?

MR. OLEFKE: I am not real sure that that is germane to this testimony.

MR. COTTINE: What type of monitoring did they conduct at your plant?

Was it on-site monitoring or was it on the site itself?

MR. OLEFKE: I think that it was outside the plant or --

MR. COTTINE: Outside perimeters?

MR. OLEFKE: That is right.

MR. COTTINE: Could you submit that information?

MR. OLEFKE: I don't have it.

MR. COTTINE: No.

Could you submit it for the record?

MR. OLEFKE: I don't know that we have a report as such.

MR. COTTINE: If one is available.

MR. OLEFKE: If one is available, we will submit it for the record.

MR. COTTINE: Okay. Fine.

Thank you very much.

JUDGE MYATT: Any other questions?

(No response.)

JUDGE MYATT: Thank you, Mr. Olefke. Thank you very much.

All right, Mr. Rowe, will you continue with your testimony.

MR. ROWE: I would like now to turn to our medical

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TOXICITY

P. J. GEHRING
THE DOW CHEMICAL COMPANY
MIDLAND, MICHIGAN

DR. PERRY GEHRING, DIRECTOR OF THE TOXICOLOGY RESEARCH LABORATORY OF HEALTH AND ENVIRONMENTAL RESEARCH FOR THE DOW CHEMICAL U.S.A. WILL NOW PRESENT AND DISCUSS DATA HE HAS SO FAR OBTAINED RELATIVE TO THE METABOLIC PATHWAYS BY WHICH THE RAT DEALS WITH VCM.

PERRY

Preliminary Studies of the Fate of Inhaled Vinyl Chloride Monomer (VCM) in Rats

Hefner, R. E. Jr., Watanabe, P. G. and Gehring, P. J.

Dow Chemical U.S.A., Health and Environmental Research
Midland, Michigan 48640

INTRODUCTION

Vinyl chloride monomer (VCM), extensively used for the production of polyvinyl chloride and other plastics, has been associated with the development of angiosarcoma and portal cirrhosis of the liver as well as other untoward effects in workers exposed to unknown but undoubtedly high concentrations of VCM. Angiosarcomas, zymbal gland carcinomas, and nephroblastomas developed in rats exposed to concentrations of VCM ranging from 50 to 10,000 ppm, 4 hours per day, 5 days per week for 12 months, and subsequently maintained and observed until death[9]. References to studies of the untoward effects of VCM in man and laboratory animals are located in this volume of The Annals of the New York Academy of Sciences.

No information is available on the fate of VCM in the mammalian organism. Such information is essential for elucidating the toxicodynamics of VCM. This would provide a rationale to assess the potential hazard of exposure to low levels of VCM. Results of preliminary studies on the fate of VCM in rats exposed via inhalation are reported herein. Prior to undertaking these studies it

was conceived that VCM might be metabolized via the alcohol dehydrogenase pathway, and if so, this pathway would very likely be saturable and that conjugation of VCM or its metabolites with glutathione and cysteine might be expected. Therefore, much of the work conducted to date has been directed at evaluating these possibilities.

METHODS

Kinetic Studies of the Uptake (Metabolism) of Inhaled Vinyl Chloride Monomer

Male Sprague-Dawley albino rats of Spartan strain weighing from 165 to 200 grams were exposed to initial concentrations of VCM gas ranging from 50.5 to 1167.0 ppm (0.13 to 2.99 mg/ℓ). Exposures ranged from 52.5 to 356.3 minutes. Figure 1 depicts the closed, recirculating 4.7ℓ inhalation apparatus in which a group of four rats were concurrently exposed. To minimize contamination of fur and skin, only the nares of the rats protruded through a rubber membrane into the chamber. Expired carbon dioxide was continuously removed from the chamber by absorption on an Ascarite© column in the recirculating system. As carbon dioxide was removed from the system, the pressure drop was detected by a mercury manometer fitted with a photoelectric cell. This activated a solenoid valve and dual syringe pump to inject makeup oxygen into the system.

The chamber atmosphere was continuously analyzed for VCM (10.9μ) by an in line Miran-I infrared analyzer (Wilks).

Using known concentrations of VCM prepared in 100ℓ Saran bags, the absorbance versus concentration adhered to the Beer-Lambert Law. During the exposures, routine checks for carbon dioxide in the chamber atmosphere were made at 4.26μ. Oxygen consumption for each experiment was determined directly by measuring the oxygen metered into the system using a dry test meter (American Meter Co.).

Prior to each exposure, the desired initial concentration of VCM was generated in the empty recirculating system and the decline in concentration was followed for a time equal to or exceeding that of the intended experiment. The decline in concentration was in accordance with first order kinetics as described by

$$dC/dt = -K_1 C_o$$

In this equation, C(ppm) equals the concentration of VCM at time t(min), C_o(ppm) equals the initial concentration of VCM, and K_1 (min^{-1}) is the rate constant for the decline in VCM concentration from the empty recirculating system. Regression analysis of the logarithm of the concentration of VCM versus time yielded K_1. Initially values for K_1 were determined before and after inclusion of rats in the chamber. These values were reproducible, therefore K_1 was not redetermined after removal of the rats in every subsequent experiment. Between experiments, the system was disassembled, cleaned, and reassembled using a new Ascarite®

column. The K_1 for each reassembled system was unique, within certain limits, which necessitated its redetermination for each experiment.

After determining the rate of decline of VCM concentration in the empty inhalation system, four rats were placed in the chamber. The chamber was then charged with the desired concentration of VCM, and the rate of decline of VCM concentration was determined as previously described. The rate of decline, K_e, followed apparent first order kinetics. After an initial equilibration of the tissues of the rats, the decline of VCM concentration from the closed system was assumed to occur via metabolism of VCM plus the background loss from the system. Since oxygen consumptions were within 10% for all experiments described herein respiratory parameters were not significantly changed. Therefore, respiratory parameters were not a factor influencing the rates of metabolism. The rate of metabolism, K_c, would therefore be given by the equation

$$K_c = K_e - K_1$$

To assess the effects of potential inhibitors of VCM metabolism, rats were pretreated by intraperitoneal injection with 320 mg/kg pyrazole (1,2-diazole) 1 hour prior to exposure, 5 ml/kg ethanol 1.5 hours prior to exposure, or 75 mg/kg SK&F-525-A (β-diethylaminoethyldiphenylpropylacetate) 0.5 hour prior to exposure. Without cleaning or reassembling the inhalation system, both untreated control rats and rats treated with the chosen potential inhibitor were exposed to the desired concentration of VCM. The percent inhibition was calculated from the equation

$$\frac{K_c \text{ (control)} - K_c \text{ treated}}{K_c \text{ control}} = \% \text{ inhibition}$$

Effects of VCM on Liver Sulfhydryl Levels

Groups of male Sprague-Dawley albino rats of Spartan strain weighing from 193 to 250 grams at initiation of the experiment were exposed to nominal concentrations of 15,000 ppm vinyl chloride for 5 days, 5000 or 500 ppm 5 days per week for 1, 3, or 7 weeks, and 50 ppm for 1 hour, 7 hours, or 5 days. The exposures were carried out in a glass-walled 160ℓ chamber under dynamic conditions with the VCM being metered into the chamber airstream. For repeated daily exposures, 7 hour exposures were conducted on the first four of five consecutive days each week. On the fifth day, if the rats were to be sacrificed, the duration of exposure was reduced to 5 to 6 hours; however, if the rats were being continued on exposure, they received a full 7 hour exposure.

The body weights and food consumption of rats exposed to 500 and 5000 ppm VCM were determined before each daily exposure and the rats were observed periodically for signs of toxicity. Between 1 and 2 PM, immediately following the fifth exposure of the designated week, the rats were killed by cervical dislocation and the livers removed and prepared for assay of sulfhydryl content. Gross pathological examinations were conducted.

The method used for the sulfhydryl assay was a modification of that described by Sedlak and Lindsay[12]. Exactly 500 mg of liver from each rat was homogenized for 1 minute in a Dounce tissue homogenizer containing 8 ml of 0.02M disodium EDTA. For the total sulfhydryl assay, a 0.5 ml aliquot of each homogenate was mixed with 1.5 ml of 0.2M tris HCl pH 9.2 buffer, 0.1 ml of 0.01M DTNB (5,5'-dithiobis(2-nitrobenzoic acid)), and 7.9 ml of methanol. A reagent blank without liver homogenate, and a sample blank, without DTNB, were also prepared. The color generated via the release of nitromercaptobenzoic acid anion was allowed to develop for 15 minutes, and the samples were centrifuged for 15 minutes at 4,000 g. Absorbance of each sample was read against the respective sample blank at 412 nm with a Beckman DB spectrophotometer. Subsequently, the molar concentration of total sulfhydryl in the sample was calculated using an extinction coefficient determined from standards of known concentrations of glutathione or cysteine. A plot of absorbance versus the concentration of cysteine or glutathione coincided with that reported by Sedlak and Lindsay[12].

The non-protein sulfhydryl content of liver was determined after precipitating out the protein by addition of 1 ml of 50% trichloroacetic acid to a 5 ml sample of liver homogenate. Each sample was diluted with 4 ml of distilled water and after 15 minutes centrifuged at 4,000 g. A 2 ml aliquot of the supernatant was mixed with 4 ml

of 0.4M tris HCl pH 8.9 buffer. Immediately before reading the absorbance against a reagent blank, 0.1 ml of 0.01M DTNB was added. Subtraction of the non-protein sulfhydryl content from the total sulfhydryl content yielded a value for protein-bound sulfhydryl.

Urine samples collected from rats exposed to 5000 ppm vinyl chloride for 4, 5, and 7 weeks were analyzed for the presence of S(2-chloroethyl)cysteine, S(2-hydroxyethyl)-cysteine, and S(2-carboxymethyl)cysteine (5 and 7 week samples only). Urine was collected for analysis by applying pressure to the posterior abdomen between the fifth and sixth hour of the fifth daily exposure on the designated week. Urine collected on the same day was pooled. For the three aforementioned compounds, 2 to 15 µl of urine were spotted directly on a 5 by 20 cm Baker-flex® silica gel plate. Also spotted were samples of urine collected from control rats and standard aqueous solutions as well as control urine to which approximately 1 µg/µl of each of the compounds had been added. The chromatograms were developed for 5 hours in a sealed glass tank containing n-butanol, acetic acid, water 80:10:10 or 60:20:20. After being air dried, the plates were sprayed with Ninspray® ninhydrin reagent and heated for 2 minutes at 80°C. The color of the spots and their R_f values were used to identify the compounds.

A urine sample collected from rats exposed to 5000 ppm vinyl chloride for 9 weeks was analyzed for the presence

of chloroacetic acid. The 10 ml urine sample was acidified with 0.1 ml of 50% v/v H_2SO_4. Subsequently, the urine sample was extracted 3 times with 2 ml of diethyl ether. The diethyl ether extract was evaporated to 0.1 ml and 2 to 15 µl of the concentrated extract and an aqueous standard containing 5% w/v chloroacetic acid were spotted on an Eastman fluorescent silica gel plate. The chromatograms were developed in a sealed glass tank for 5 hours using the aforementioned solvent systems. After air drying the plates, they were examined under ultraviolet light to determine the location of spots. Subsequently, the plates were treated with ninhydrin as described previously.

RESULTS

Kinetic Studies on the Metabolism of Inhaled VCM

Typical declines in the concentration of VCM in the inhalation apparatus containing 4 rats and initial concentrations of approximately 50 or 1000 ppm are shown in Figure 2. Also shown are the corresponding declines in the concentration of VCM from the unoccupied chamber. As indicated in the methods, the rate of these declines, K_e and K_1, respectively, were determined by regression analysis. The rate of metabolism, K_c, was assumed equal to $K_e - K_1$. For seven separate exposures to concentrations of VCM ranging from 50 to 105 ppm, the mean and standard deviation for the apparent first order rate constant, K_c, were $-8.04 \times 10^{-3} \pm 3.40 \times 10^{-3}$ min^{-1}. This corresponds to a one-half life ($t_{1/2}$) of 86 minutes.

For five separate exposures to concentrations of VCM ranging from 220 to 1167 ppm, K_c was $-2.65 \times 10^{-3} \pm 1.35 \times 10^{-3}$ min^{-1}. This corresponds to a $t_{1/2}$ of 261 minutes. As indicated by the standard deviations, there was little variation of K_c within the indicated range of concentration. Furthermore, there was no consistent trend for the values of K_c within this range.

Administration of 320 mg/kg pyrazole, an inhibitor of alcohol dehydrogenase, xanthine oxidase and other enzymes[3], 1 hour before exposure to 65 and 1234 ppm VCM resulted in 71.2 and 86.9% inhibition of metabolism of VCM, respectively (Figure 3).

Because of the lack of specificity of pyrazole as an enzyme inhibitor, 5 ml/kg 95% ethanol was administered to rats in an attempt to specifically inhibit alcohol dehydrogenase activity. In rats exposed to initial concentrations of 56 and 97 ppm VCM, ethanol pretreatment caused 96.0 and 82.9% inhibition of VCM metabolism, respectively. When rats were pretreated with ethanol and exposed to initial concentrations of 1025 and 1034 ppm VCM, inhibition of metabolism was 46.5 and 35.7%, respectively. Figure 4 illustrates the inhibition for separate experiments conducted at extremes of initial VCM concentrations.

Pretreatment of rats with 75 mg/kg SK&F-525-A, an inhibitor of some types of microsomal oxidases[13] resulted in no inhibition

of metabolism of VCM in rats exposed to initial concentrations of 65 ppm and an 18.8% inhibition in those exposed to 1038 ppm (Figure 5).

Effect of Inhaled VCM on Liver Sulfhydryl Levels

No antemortem or postmortem signs of toxicity were noted in rats exposed to any concentration of VCM used in these experiments. Analysis of food consumption data for rats exposed to nominal concentrations of 500 or 5000 ppm VCM, and unexposed controls revealed no statistically significant differences. In addition, no significant difference was found in the water consumption of rats exposed to 5000 ppm and controls. Throughout the durations of observation, the mean body weights of rats exposed to the various concentrations of VCM were essentially the same as those of the respective controls. No gross pathological lesions related to exposure of VCM, were found in any of the rats.

Table 1 shows the non-protein sulfhydryl content of the liver of rats exposed to 50, 500, 5000 or 15,000 ppm VCM for the indicated durations. Values for concurrent controls are also given. In Figure 6, these data are summarized and expressed as the percent depression of the non-protein sulfhydryl content of the liver as a function of exposure concentration and duration of exposure. Significant reductions in the levels of non-protein sulfhydryl occurred in rats exposed to 50 ppm VCM for 7 hours, 500 and 5000 ppm for 1 and 3 weeks, and 15,000 ppm for 1

week. There is no difinitive association between exposure concentration and the degree of depression. The degree of depression decreases with continued exposure which suggests compensatory mechanisms are responding to relieve this biochemical effect induced by VCM.

The protein bound sulfhydryl content of the liver of rats exposed to 50, 500, 5000 or 15,000 ppm VCM for the indicated durations were not significantly different from those of the concurrent controls. This was not unexpected because the sulfhydryl groups of protein have been shown not to be readily akylated unless denaturation of the protein renders them available for alkylation[14].

Effect of Ethanol Administration of VCM Induced Depression of Non-Protein Sulfhydryl in Liver

In this experiment, four rats pretreated with 5 ml/kg ethanol and four untreated control rats were exposed to 1070 ppm VCM. Following 105 minutes of exposure, the concentration of non-protein sulfhydryl in the liver was determined. For those pretreated with ethanol, the depression of non-protein sulfhydryl was 77.0 $\pm$ 12.8%, while for controls it was 95.0 $\pm$ 3.4%. These levels of depression were significantly different as determined by Student's "t" test, $p<0.05$. Johnson[7] has reported that ethanol alone does not affect the non-protein sulfhydryl content of the liver.

Metabolites of VCM

Preliminary results which must be viewed with considerable reservation have been obtained from studies in which rats were exposed to 5000 ppm unlabeled VCM for 4, 5 or 7 weeks. Chromatograms of urine collected from rats after each of these exposure durations were comparable. S(2-hydroxyethyl)cysteine (R_f 0.26-0.28 in 80:10:10 n-butanol, acetic acid, water) appeared to be present. S(2-chloroethyl)cysteine and S(2-carboxymethyl)cysteine were not detected; however, it is conceivable that the latter compound was not adequately resolved from the urine background.

In another experiment, chromatograms of urine from rats exposed to 5000 ppm VCM for 9 weeks revealed the presence of monochloroacetic acid (R_f 0.74 using the aforementioned solvent system). The spots for monochloroacetic acid were visualized under ultraviolet light on the fluorescent plates and did not develop with ninhydrin reagent.

Studies of the metabolism of VCM were terminated until methods were developed to synthesize ^{14}C-VCM. ^{14}C-VCM in a liquid state polymerized even when an inhibitor was present and a temperature of -70°C was maintained. Recently, a method has been developed to synthesize ^{14}C-VCM in a gaseous state from 1,2-dichloroethane. In the gaseous state ^{14}C-VCM is relatively stable. Currently,

the methodology is being refined to allow synthesis of ^{14}C-VCM with reproducible specific activity.

Using ^{14}C-VCM, three 180 g. male rats have been exposed in the closed recirculating system for 65 minutes. The initial concentration of ^{14}C-VCM with a specific activity of 1.155 mCi/mmole was 49 ppm. Assuming equivalent uptake of VCM by the 3 rats, each rat received 0.49 mg/kg VCM. Immediately following exposure, the rats were removed from the chamber and placed in Roth type metabolism cages which allow separate collection of urine, feces, expired carbon dioxide and any expired VCM.

Within 15 hours post exposure, a mean of 58.0% of the ^{14}C activity had been excreted in the urine, 2.7% in the feces, and 9.8% as expired carbon dioxide. By 75 hours post exposure, 67.1% had been excreted in the urine, 3.8% in the feces, and 14.0% as expired carbon dioxide. Only a trace, 0.02% of the dose, was expired as VCM and trapped on activated carbon. After 75 hours, 1.6% of the dose remained in the liver, 3.6% in the skin, 0.2% in the kidneys and 7.6% in the remaining carcass. The mean percent of the assumed dose recovered from the three rats was 97.9%.

Various chromatographic techniques are being evaluated for separation and identification of the ^{14}C labeled urinary metabolites. S(2-hydroxyethyl)cysteine and S(2-carboxymethyl)cysteine and their respective N-acetyl derivatives appear to be likely metabolites. Ultimate verification of metabolites will be determined by gas

chromatographic - mass spectroscopic analysis. In the experiment just described, monochloroacetic acid has not been detected.

In summary, metabolism studies have demonstrated tentatively the following:

a) VCM is quite readily metabolized to polar metabolites which are excreted predominantly in the urine of rats exposed via inhalation to an initial concentration of 50 ppm. Smaller amounts of VCM are excreted in the expired air as carbon dioxide and in the feces. Very little is excreted in expired air as unchanged VCM.

b) A significant but small amount is retained in tissue, particularly liver, as long as 75 hours post exposure.

c) Metabolites excreted in the urine appear to be conjugated with glutathione and/or cysteine through covalent linkage to the sulfhydryl group. This is consistent with the reduction of the non-protein free sulfhydryl levels in the livers of exposed rats. Preliminary <u>in vitro</u> experiments have shown that direct conjugation of vinyl chloride with cysteine or glutathione in aqueous solutions occurs to a small degree but very slowly.

d) Monochloroacetic acid also appears to be a metabolite of VCM, when rats were exposed to 5000 ppm for an extended time.

DISCUSSION

Because of the preliminary nature of the studies reported herein, the results and subsequent discussion must not be considered conclusive. Justification for premature publication of some of the data contained herein is the magnitude of the impact of recently revealed toxicological effects of VCM and the urgent need for communication of even preliminary results.

The studies reported herein have demonstrated reliably in some instances and tentatively in others the following:

a) Rats exposed to concentrations of VCM below 100 ppm metabolize the compound fairly readily and in accordance with first order rate kinetics, $t_{1/2}$ = 86 minutes.

b) When exposed to a concentration of VCM exceeding 200 ppm, its rate of metabolism was reduced, $t_{1/2}$ = 261 minutes. This indicates that the predominate pathway for metabolism of VCM by rats exposed to 100 ppm or less is saturable. Residual metabolism at concentrations exceeding 200 ppm may be via this pathway in conjunction with additional pathway(s).

c) Pyrazole inhibits the metabolism of VCM suggesting that metabolism of VCM is via alcohol dehydrogenase.

d) Stronger evidence for the metabolism of VCM by alcohol dehydrogenase was its inhibition by the administration of ethanol. This inhibition was less pronounced in rats exposed to 1000 ppm than in rats exposed to 100 ppm or less, suggesting that metabolism via pathways other than that of alcohol dehydrogenase occurs in rats exposed to 1000 ppm VCM.

e) SK&F-525-A does not affect the metabolism of VCM by rats exposed to 65 ppm VCM but there is an indication that it slightly depresses metabolism by rats exposed to 1038 ppm VCM. This suggests that in rats exposed to concentrations of VCM which exceed the capacity of the alcohol dehydrogenase pathways metabolism may occur via oxidases in the microsomes.

f) Monochloroacetic acid was found in urine of rats exposed to 5000 ppm VCM daily for 9 weeks.

g) Exposure to VCM reduces the non-protein sulfhydryl concentration of liver. This reduction is not definitively associated with the exposure concentration of VCM in a range of 50 to 15,000 ppm. There is a tendency for the reduction to become less pronounced with repeated daily exposures. These results are consistent with a

saturable mechanism for the metabolism of VCM followed by conjugation of the metabolites of VCM with glutathione and/or cysteine.

h) The administration of ethanol significantly reduces the depression of the concentration of non-protein sulfhydryl in the livers of rats caused by exposure to 1000 ppm VCM for 105 minutes.

i) In rats exposed to 49 ppm, VCM is metabolized to polar products which are excreted predominantly in the urine. These products appear to be derived following initial metabolism of VCM and subsequent conjugation of the products with glutathione and/or cysteine through covalent binding with the sulfhydryl. A small but significant fraction of VCM is metabolized to CO_2 and expired. An even smaller but significant amount of ^{14}C activity appears to be retained in the liver primarily, but also in other tissues as long as 75 hours post exposure.

Considering the results in toto, we hypothesize that in rats exposed to concentrations of VCM below 100 ppm, VCM is predominantly metabolized via sequential oxidation to 2-chloroethanol, chloroacetaldehyde, and monochloroacetic acid by the alcohol dehydrogenase pathway.

$$ClHC = CH_2 \longrightarrow ClH_2C\text{-}CH_2OH \xrightarrow[\text{dehydrogenase}]{\text{alcohol}}$$

$$ClH_2C\text{-}CHO \longrightarrow ClH_2C\text{-}COOH$$

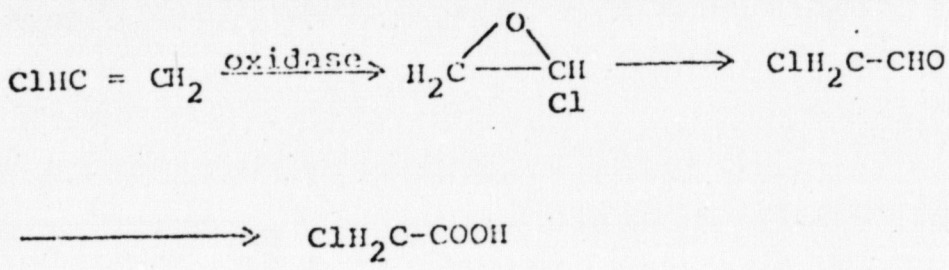
Only small amounts, if any, of monochloroacetic acid are formed at low doses because chloroacetaldehyde reacts rapidly with the sulfhydryl of glutathione and cysteine[8]. This conjugation accounts for the lack of dose related reduction in the non-protein sulfhydryl content of the liver of rats exposed to 50 through 15,000 ppm VCM.

Alternate pathways of VCM metabolism which may be involved at high doses are at this time purely speculative. However, at 200 ppm, metabolism by the more rapid alcohol dehydrogenase pathway appears to be saturated, and metabolism via oxidation of the accumulating 2-chloroethanol may occur as follows:

$$ClH_2C{-}{-}CH_2OH \xrightarrow[\text{catalase}]{H_2O_2} ClH_2C{-}{-}CH_2OOH \rightarrow ClH_2C{-}{-}CHO$$

Carter, et. al.[3] have demonstrated that microsomal oxidation of ethanol in vitro proceeds via the formation of hydrogen peroxide and catalase which subsequently forms a peroxide of ethanol. Acetaldehyde is the end product of this oxidation. It is conceivable that a similar oxidation of 2-chloro-ethanol occurs.

In addition to this series of reactions, a direct expoxi-dation of VCM may occur as follows:

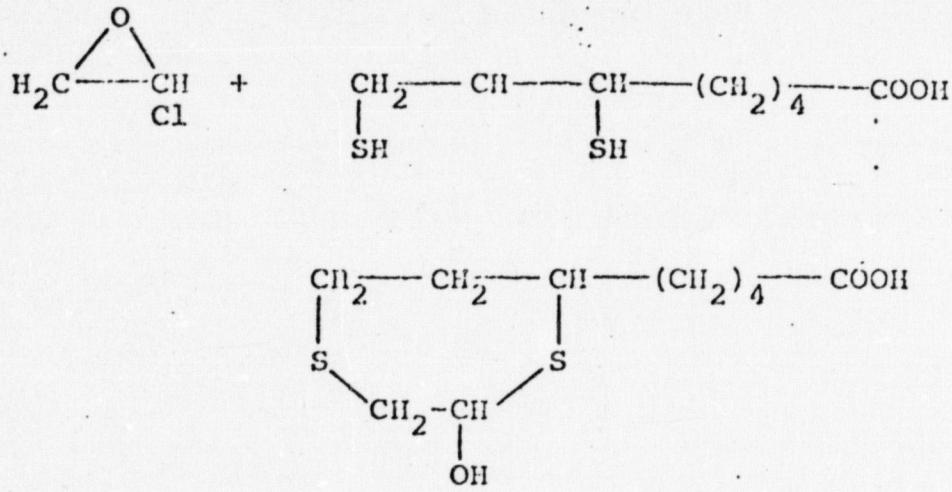


Zief, et. al.[15] have shown that chloroethylene oxide spontaneously rearranges to chloroacetaldehyde. Such mechanisms would explain why SK&F-525-A causes a slight inhibition of metabolism in rats exposed to 1038 but not 65 ppm VCM. Also it may explain why monochloroacetic acid may be excreted by rats exposed to 5000 ppm but not 50 ppm VCM. In the former case, chloroacetaldehyde is produced by each of the hypothesized pathways which may result in a greater amount being oxidized to monochloroacetic acid than being conjugated with glutathione and/or cysteine.

Inferences from the results of these studies about the toxicodynamics of VCM are premature, but worth mentioning. First, the saturation of a primary metabolic pathway for VCM degradation and redirection through other pathways provides some hope that a threshold concentration for the untoward effects of VCM may exist. Metabolites of VCM formed only via the alternate pathways may constitute the ultimate toxin and carcinogen.

It has been reported that the administration of cysteine or glutathione provides protection against the untoward effects of various aliphatic and aromatic mustards, triethylenemelamine, X-rays, and ionizing radiation.[1,2,5,10,14] Conceivably, cysteine and glutathione may provide a natural defense against tumor producing free radicals generated within the body, as well as synthetic or naturally occurring alkylating agents which are absorbed into the body. Therefore, reduction of the non-protein sulfhydryl content of the liver in animals exposed to VCM may constitute predisposition to toxicity and carcinogenicity mediated via other materials.

Finally, the speculated formation of chloroethylene oxide seems particularly pertinent insofar as postulation of the mechanism of carcinogenesis. This compound is undoubtedly a very active difunctional alkylating agent. It is most interesting that inorganic arsenicals have been reported to cause untoward hepatic effects, portal cirrhosis and angiosarcoma, like those reported for VCM.[11] The mechanism of toxicity for arsenic has been shown to occur via its reaction with 6,8-dithiooctanoic acid (α-lipoic acid).[6] In this reaction arsenic forms a stable bridge between the two sulfhydryl groups. If chloroethylene oxide were formed, it would readily react with α-lipoic acid, bridging the sulfhydryl groups like arsenic.



Although this postulated mechanism is highly speculative, the rarity of materials known to produce untoward hepatic effects like those of VCM must be given some weight.

ACKNOWLEDGMENTS

These studies were supported in part by a grant from the Manufacturing Chemists Association. The technical advise of Dr. B.K.J. Leong in designing the inhalation apparatus and the critical review of the manuscript by Dr. V. K. Rowe is gratefully acknowledged.

6/21/74

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Captions for Figure and the Table

Figure 1 Closed Recirculating Inhalation Apparatus Used for Exposing Rats to VCM.

Figure 2 Typical declines in VCM concentration with time at approximately 50 and 1000 ppm VCM exposure concentrations. Also shown are the respective declines in VCM concentration for the unoccupied inhalation apparatus.

Figure 3 Declines in VCM concentration with time at 65 and 1234 ppm VCM exposure concentrations for both pyrazole pretreated and untreated control rats. Also shown are the respective declines in VCM concentration for the unoccupied inhalation apparatus.

Figure 4 Declines in VCM concentration with time at 56 and 1034 ppm VCM exposure concentrations for both ethanol pretreated and untreated control rats. Also shown are the respective declines in VCM concentration for the unoccupied inhalation apparatus.

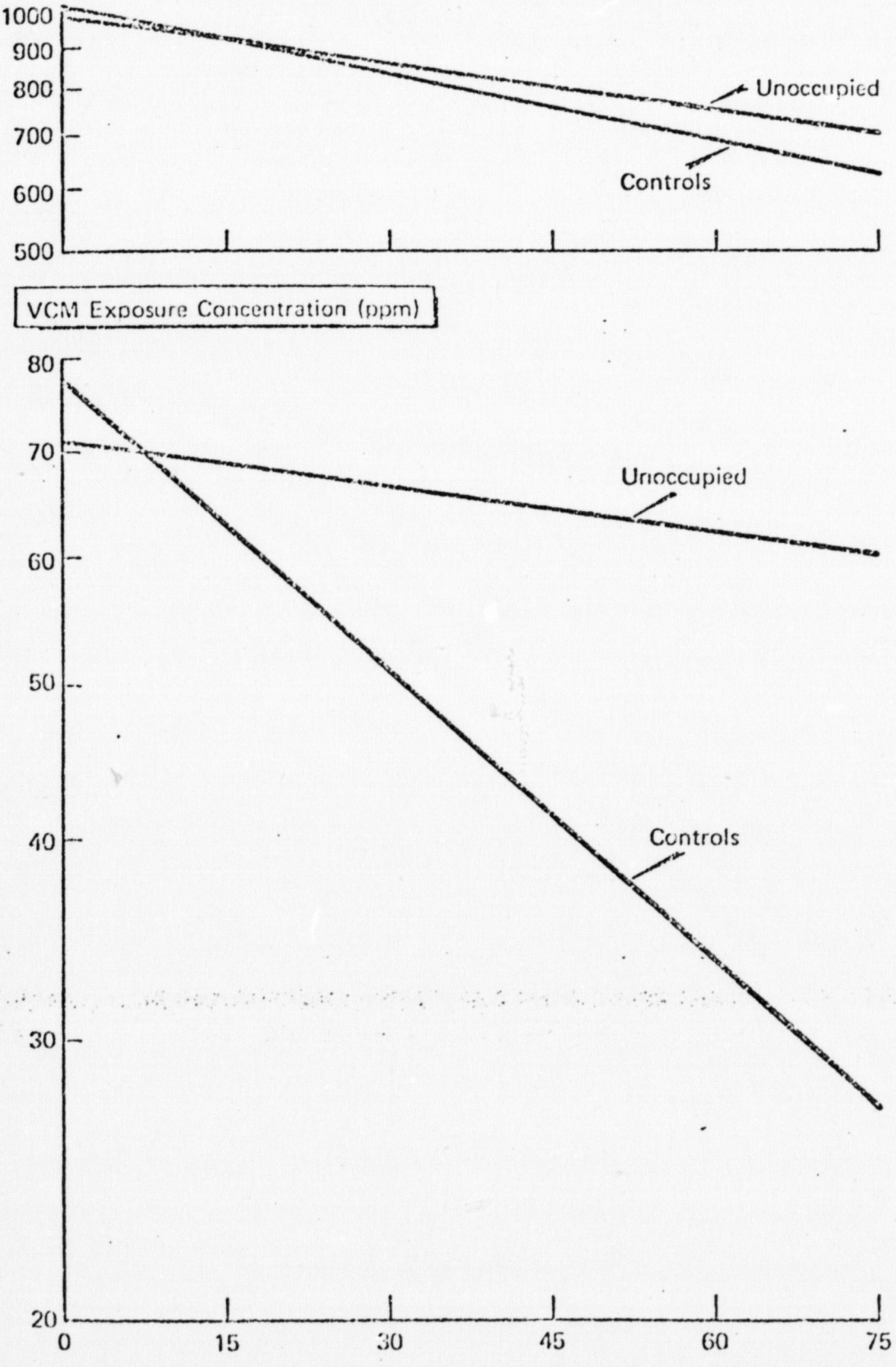
Figure 5 Declines in VCM concentration with time at 65 and 1038 ppm VCM exposure concentrations for both SK&F-525-A pretreated and untreated control rats. Also shown are the respective declines in VCM concentration for the unoccupied inhalation apparatus.

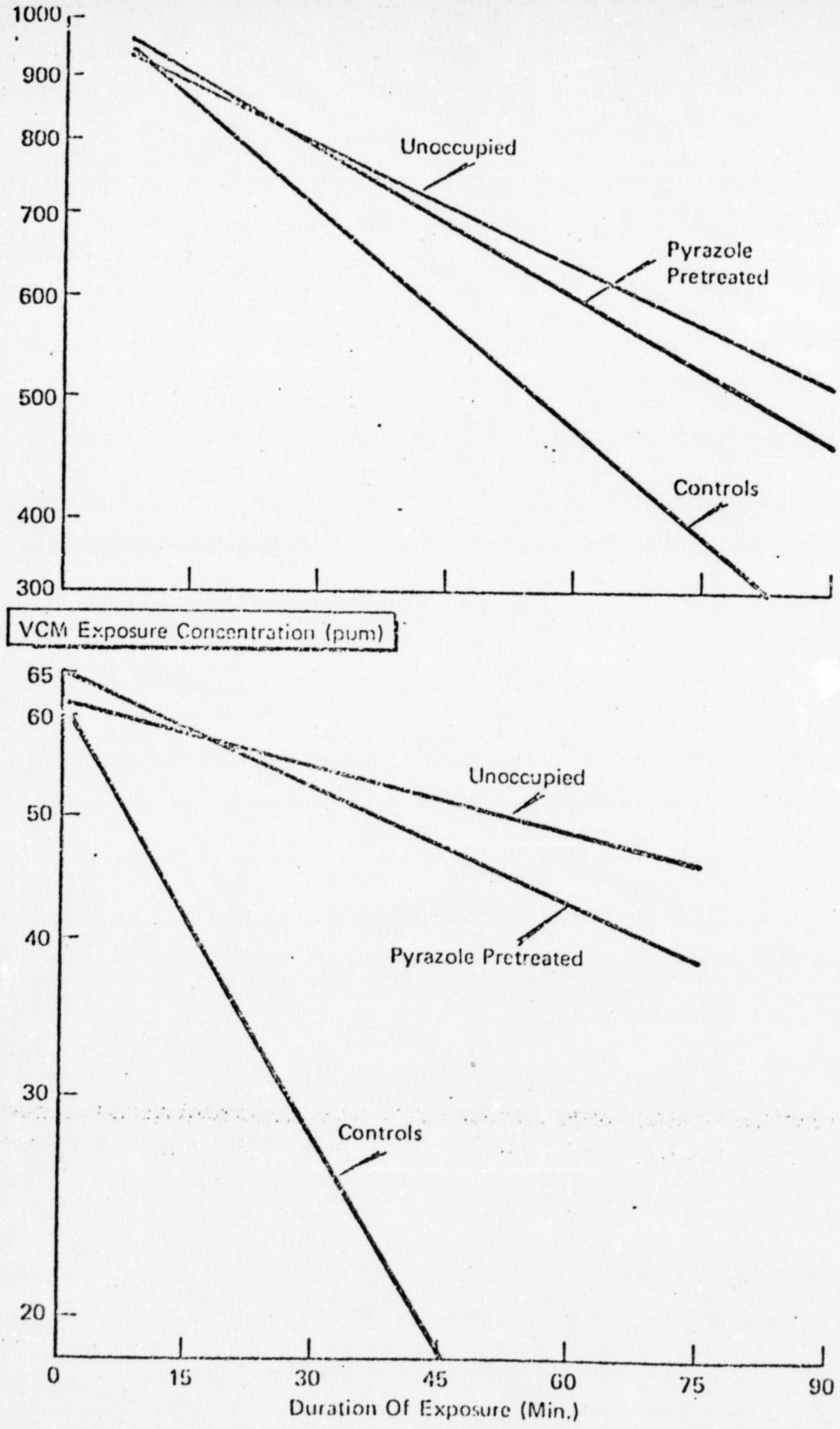
Figure 6 Percent depression of non-protein sulfhydryl in the liver of rats as a function of VCM exposure concentration and duration of exposure.

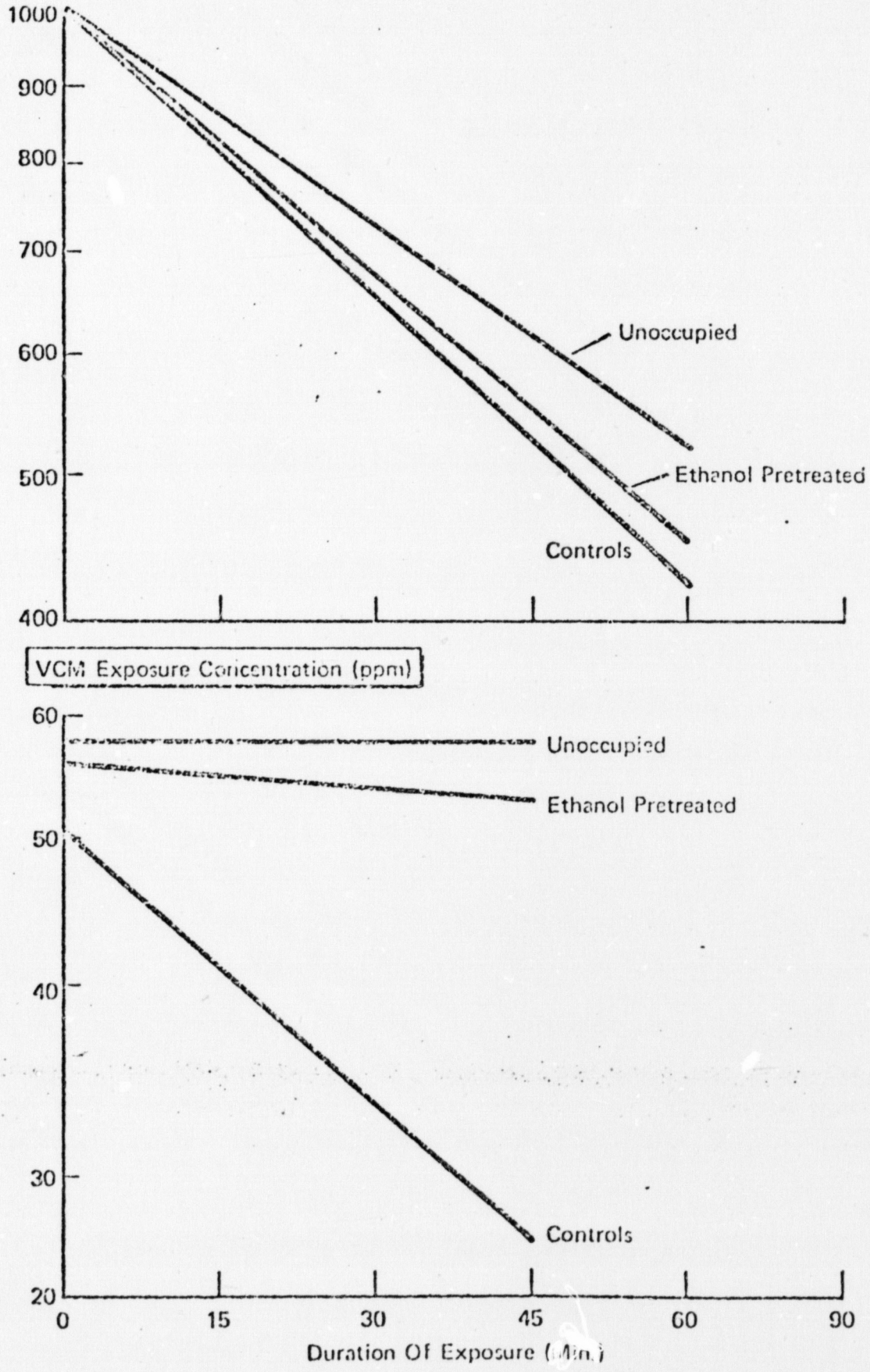
Table 1 Non-protein sulfhydryl content (1×10^{-8} moles SH/mg of liver) of rats exposed to 50, 500, 5000 or 15,000 ppm VCM and concurrent controls.

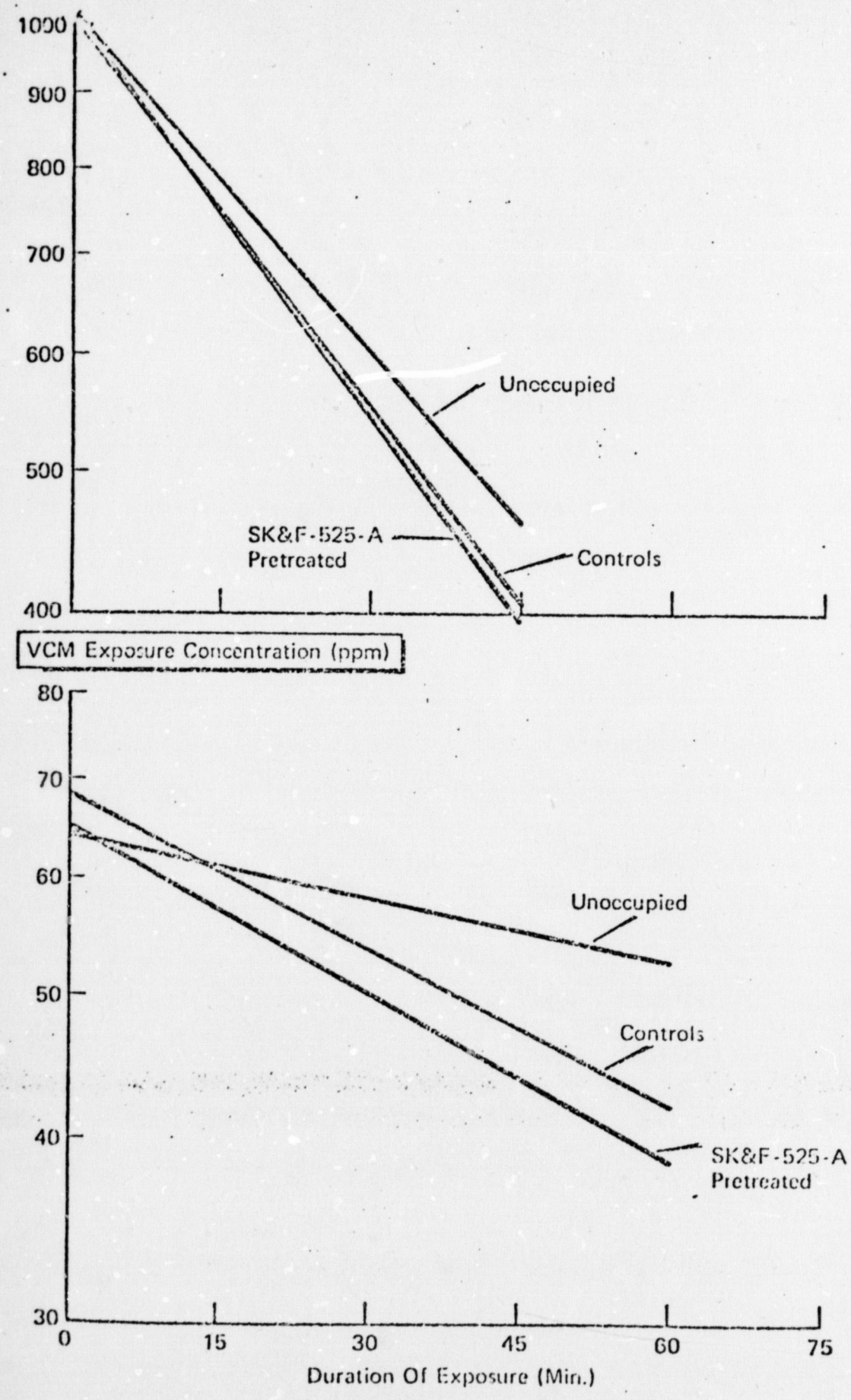
Figure 6 Percent depression of non-protein sulfhydryl in the liver of rats as a function of VCM exposure concentration and duration of exposure.

Table 1 Non-protein sulfhydryl content (1×10^{-8} moles SH/mg of liver) of rats exposed to 50, 500, 5000 or 15,000 ppm VCM and concurrent controls.

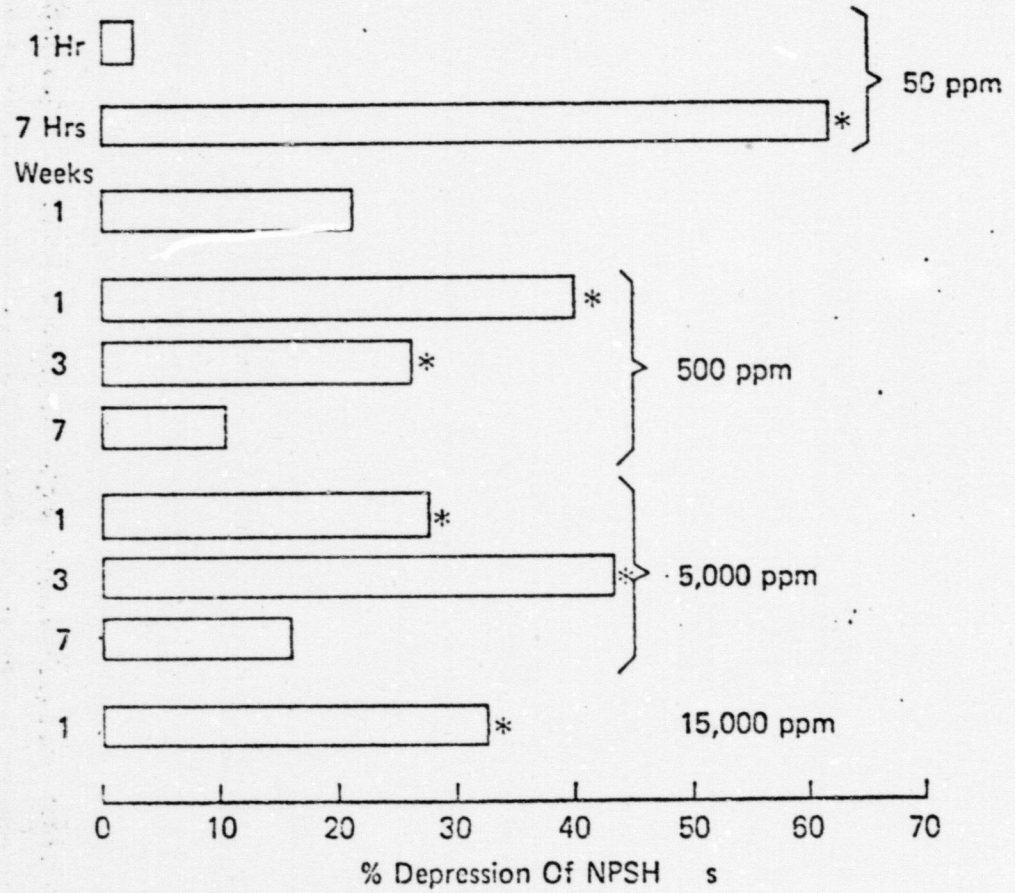

1000
900
800
700
600
500
Unoccupied
Controls
VCM Exposure Concentration (ppm)
80
70
60
50
40
30
20
Unoccupied
Controls
0
15
30
45
60
75
Duration Of Exposure (Min.)


1000
900
800
700
600
500
400
300
Unoccupied
Pyrazole
Pretreated
Controls
VCM Exposure Concentration (ppm)
65
60
50
40
30
20
Unoccupied
Pyrazole Pretreated
Controls
0
15
30
45
60
75
90
Duration Of Exposure (Min.)


1000
900
800
700
600
500
400
Unoccupied
Ethanol Pretreated
Controls
VCM Exposure Concentration (ppm)
60
50
40
30
20
Unoccupied
Ethanol Pretreated
Controls
0
15
30
45
60
90
Duration Of Exposure (Min.)


1000
900
800
700
600
500
400
Unoccupied
SK&F-525-A
Pretreated
Controls
VCM Exposure Concentration (ppm)
80
70
60
50
40
30
Unoccupied
Controls
SK&F-525-A
Pretreated
0
15
30
45
60
75
Duration Of Exposure (Min.)

VINYL CHLORIDE CONCENTRATION



$$\% \text{ Depression} = \frac{\text{Mean Conc. Of Controls} - \text{Mean Conc. Of Exposed}}{\text{Mean Conc. Of Controls}}$$

*Significantly depressed using Students "T" test, $p < 0.05$

	VCM CONCENTRATION							
Duration of Exposure	15,000 ppm	Concurrent Controls	5,000 ppm	Concurrent Controls	500 ppm	Concurrent Controls	+50 ppm	Concurrent Controls
7 hours per day for 5 days	*0.29 ±0.08	0.42 ±0.07	*0.33 ±0.02	0.46 ±0.03	*0.35 ±0.09	0.58 ±0.06	0.34 ±0.01	0.43 ±0.09
7 hours per day 5 days per week for 3 weeks			*0.41 ±0.03	0.72 ±0.03	*0.45 ±0.06	0.61 ±0.08		
7 hours per day 5 days per week for 7 weeks			0.59 ±0.08	0.70 ±0.02	0.58 ±0.06	0.64 ±0.08		

+A single 1 hour exposure to 50 ppm VCM resulted in 0.64±0.05 and 0.65±0.06 for the concurrent controls. A single 7 hour exposure to 50 ppm VCM resulted in 0.17±0.07 and 0.44±0.08 for the concurrent controls.

*Significantly different using Students "t" test, $p<0.05$.

CURRICULUM VITAE

Perry James Gehring

Birthplace: Yankton, South Dakota

Birthdate: March 15, 1936

Married: 1959, Barbara Tennis

Children: Daniel, 1961; Matthew, 1964; Elizabeth, 1966; Heidi, 1971.

Education: Elementary and Secondary Schools
Yankton, S. Dakota

Graduated University of Minnesota in 1960 with B.S. and D.V.M. degrees.

Attended Iowa State University 1960-1961; Graduate work in physiology at Baylor Univ. Summer, 1961, no degree.

Graduated University of Minnesota, Ph.D. in 1965. Major in Pharmacology and Minor in Physical Chemistry. Thesis: The Interrelationship Between Thallium and Potassium in Animals.

Employment: 1960-1961, Iowa State University; Research Associate in Dept. of Veterinary Physiology and Pharmacology. Financed by Atomic Energy Commission.

1961-1965, University of Minnesota, Research Fellow in Dept. of Veterinary Physiology and Pharmacology. Financed by National Institute of Health.

September 1, 1965, The Dow Chemical Company, Research Pharmacologist.
June, 1968, Group Leader - Biochemical Research Laboratory, Toxicology Research.

November 15, 1968, Associate Professor, Pharmacology Dept. Michigan State Univ.

September 1, 1970, Assistant Director, Toxicology Research Laboratory, The Dow Chemical Company, Midland, Michigan

December 11, 1973, Director, Toxicology Research Laboratory, The Dow Chemical Company Midland, Michigan

Professional Organization Memberships:

Society of Toxicology
American Society of Pharmacology and Experimental Thereapeutics.
New York Academy of Sciences
Minnesota Veterinary Medical Association

Other Professional Activities:

Board of Editors of the Journal Toxicology and Applied Pharmacology.
Visiting Professor, Dept. of Pharmacology, Michigan State Univ. E. Lansing, Michigan

Honors-Recognitions:

Undergraduate

Graduated with honors
Scholastic All-Big Ten Conference Football Team
Scholastic All American Football Team, Honorable mention on others.
Big Ten Conference Medal, 1958 for most outstanding combination of athletic and scholastic performance.
Associated Press and United Press Lineman of the Week, twice 1956 & 1957
North-South All Star Football Game, 1958

Graduate

U. S. Public Health Service - Postdoctoral Research Grant.

Professional

The Deans Advisory Council, Michigan State Univ. 1968-1970, Elected Chairman 1969.

Curriculum Committee, College of Veterinary Medicine, Michigan State Univ. 1969.

Program Committee for Annual Meeting, Society of Toxicology, 1973.

Recipient of U. S. Public Health Service Research Grant, 1968.

Member of Scientific Committee of the Animal Drug Section, Animal Health Institute.

Listed in:
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Who's Who in the Midwest
Who's Who in America
Who's who in the World

Revised 1/23/74

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Revised 1/24/74

SUMMARY AND CONCLUSIONS

V. K. ROWE
THE DOW CHEMICAL COMPANY
MIDLAND, MICHIGAN

IN SUMMARY, I WOULD FIRST LIKE TO REDIRECT YOUR ATTENTION TO THAT PORTION OF DR. GEHRING'S PRESENTATION WHEREIN HE REFERRED TO STUDIES WHICH HAVE BEEN UNDERTAKEN TO PROVIDE A BASIS FOR BETTER UNDERSTANDING THE MECHANISM OF ACTION OF VINYL CHLORIDE MONOMER. PRELIMINARY DATA SUGGEST THAT THE MATERIAL MAY BE METABOLIZED VIA DIFFERENT PATHWAYS DEPENDING UPON THE MAGNITUDE OF EXPOSURE. THE POSSIBILITY THAT THE ULTIMATE CARCINOGEN MAY BE A METABOLITE FORMED BY A SECONDARY OR EVEN A TERTIARY PATHWAY WHEN THE PRIMARY PATHWAY IS SWAMPED IS SPECULATIVE, BUT SHOULD NOT BE DISREGARDED WITHOUT TESTING. SIMILARLY, THE POSSIBILITY THAT THE MATERIAL PER SE OR A PRIMARY METABOLITE IS DIRECTLY RESPONSIBLE FOR THE CARCINOGENIC ACTION ALSO NEEDS TO BE DETERMINED.

IT ALSO SEEMS ABSOLUTELY NECESSARY TO US TO DETERMINE WHICH ANIMAL SPECIES IS MOST LIKE MAN IN ITS METABOLISM OF VCM SO THAT THAT ANIMAL SPECIES CAN BE USED IN FUTURE TOXICOLOGICAL WORK WITH VCM. AT PRESENT WE DO NOT KNOW HOW MUCH SIGNIFICANCE TO ATTACH TO THE DOSE-RESPONSE DATA BEING DERIVED FROM THE VARIOUS SPECIES BEING TESTED.

ANSWERS TO THESE QUESTIONS ARE URGENTLY NEEDED. WE URGE THAT OTHERS ALSO PUT THEIR SHOULDERS TO THIS WHEEL AS RAPIDLY AS POSSIBLE.

NEXT, I WOULD LIKE TO REEMPHASIZE THE FOLLOWING POINTS MADE BY PREVIOUS SPEAKERS, WHICH WE FEEL ARE SUPPORTED BY THE LONG AND FAVORABLE EXPERIENCE OF THE DOW CHEMICAL COMPANY IN THE MANUFACTURE AND USE OF VINYL CHLORIDE.

IN KEEPING WITH OUR PRACTICE TO KEEP CONCENTRATIONS AS FAR BELOW ANY OSHA STANDARDS OR SELF-IMPOSED GUIDELINES AS IS REASONABLY FEASIBLE, DOW CHEMICAL U.S.A. IS GENERALLY OPERATING WITHIN AN 8-HOUR TIME WEIGHTED AVERAGE CONCENTRATION OF 10 PPM; HOWEVER, BRIEF MALFUNCTIONS AND OTHER TEMPORARY SITUATIONS OCCASIONALLY RESULT IN SHORT-TERM CONCENTRATIONS IN EXCESS OF 10 PPM. BASED ON THE DATA WE HAVE, WE BELIEVE OUR PLANTS ARE BEING OPERATED IN AN APPROPRIATE MANNER.

SPECIFIC SITUATIONS SHOULD DICTATE THE SELECTION OF RESPIRATORY PROTECTIVE EQUIPMENT. EFFECTIVE CARTRIDGE AND CANISTER MASKS ARE AVAILABLE AND SHOULD BE PERMITTED IN SITUATIONS WHERE RAPID EGRESS MAY BE NECESSARY AND/OR WHERE THE AIR CONCENTRATION IS CONTINUOUSLY MONITORED AND KNOWN TO BE BELOW 50 PPM.

EXCESSIVE REQUIREMENTS FOR THE USE OF RESPIRATORS AND PROTECTIVE CLOTHING MAY WELL RESULT IN INCREASED RISK AND INJURY TO WORKERS DUE TO STRESS AND IMPAIRMENT OF VISION, HEARING, MOBILITY, DEXTERITY AND AGILITY.

PROVISIONS SHOULD BE MADE FOR CONTINUOUS AREA MONITORING IN

ADDITION TO PERSONNEL MONITORING. CONTINUOUS AREA MONITORING PROVIDES THE EARLY DETECTION OF EQUIPMENT FAILURE AND, WHEN EQUIPPED WITH AN ALARM SYSTEM, ALERTS THE EMPLOYEE SO THAT APPROPRIATE PROTECTIVE EQUIPMENT CAN BE USED TO PREVENT EXPOSURE. THE MONITOR ALSO PROVIDES DATA WHICH IS USEFUL IN CALCULATING EMPLOYEES' EXPOSURE ON A TIME WEIGHTED BASIS.

THE ANALYTICAL METHOD SELECTED FOR MONITORING WILL DEPEND UPON EACH PLANT SITUATION. ONLY SOMEONE FAMILIAR WITH THE PLANT SITUATION CAN DESIGN AN APPROPRIATE MONITORING SYSTEM

PERIODIC MEDICAL EXAMINATIONS AND CLINICAL STUDIES INDICATE NO EVIDENCE OF ANY ADVERSE EFFECT ON ANY ORGAN SYSTEM ATTRIBUTABLE TO VINYL CHLORIDE IN A POPULATION WITH RANDOM PLANT EXPOSURES UP TO 200 PPM.

WE HAVE HAD NO CASES OF ACROOSTEOLYSIS IN OUR WORK FORCE. NOR, IN EXPOSURES UP TO 200 PPM, HAVE WE SEEN ANY MEDICAL ABNORMALITIES ATTRIBUTABLE TO VINYL CHLORIDE.

WHEN DATA FROM WORKERS WHO WERE IN DOW'S HIGH EXPOSURE CATEGORY ARE SEPARATED FROM THE REST, THERE WAS A SUGGESTION OF AN INCREASE IN DEATHS DUE TO MALIGNANCY, 9 VERSUS 5.1 HOWEVER, WHEN THE WHOLE POPULATION EXPOSED TO VINYL CHLORIDE WAS CONSIDERED, THERE WAS NO DIFFERENCE.

WE HAVE FOUND NO EVIDENCE OF ANY DEATHS DUE TO ANGIOSARCOMA OR LIVER MALIGNANCY OF ANY KIND IN OUR WORKERS EXPOSED TO VINYL CHLORIDE.

WE CAN ONLY CONCLUDE THAT THE ABSENCE OF THE SIGNS AND SYMPTOMS NOTED MUST BE ASSOCIATED WITH THE OVERALL LOW EXPOSURE LEVELS OUR EMPLOYEES HAVE EXPERIENCED. THE SIGNIFICANCE OF THESE OBSERVATIONS IS EXTREMELY IMPORTANT IN CONSIDERING THE FUTURE REGULATIONS DEALING WITH THE HANDLING AND USE OF VINYL CHLORIDE MONOMER.

2 4(6)

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MEDICAL SURVEILLANCE

R. R. Cook
The Dow Chemical Company
Midland, Michigan

MEDICAL SURVEILLANCE

My name is Dr. Ralph Cook. I am a physician at the Midland Division of Dow Chemical U.S.A. I obtained my medical degree from Wayne State University. I received residency training in Occupational Medicine and a Masters Degree in Public Health from University of Michigan. I have completed requirements for certification in Occupational Medicine and have taken my board examination. While in the military I worked in the toxicology laboratory of the Army Environmental Hygiene Agency, Edgewood Arsenal, Maryland. At the present time I am involved in a study for the Division of Medical Sciences, National Research Council under contract to the Environmental Protection Agency. I came to Dow two years ago and am currently in charge of the Division's Health Inventory Program.

Today, I would like to report an analysis of selected health surveillance data on 335 chemical workers who had industrial exposures to vinyl chloride. The details of their exposures have already been reviewed by Mr. Daniel.

In the clinical parameters considered in our study, there was nothing of statistical significance below vinyl chloride levels of 200 ppm. Above this level only diastolic blood pressure showed a statistically significant deviation.

We have provided employee periodic health examinations to a varying degree for over twenty years. I refer you to the American Industrial Hygiene Association Journal (33, 19 (1972)) in which C. G. Kramer and J. E. Mutchler of The Dow Chemical Company correlated clinical and environmental measurements for workers exposed to vinyl chloride prior to 1967. Their findings "suggest that repeated exposure to vinyl chloride at TWA levels of 300 ppm or above for a working lifetime together with very low levels of vinylidene chloride may result in slight changes in certain physiological and clinical laboratory parameters. The possibility of some impairments in liver function tests must be considered, even though no overt clinical disease was evident in any of the individuals studied."

Since 1967 we have utilized multiphasic health screening techniques to evaluate our employees health status. We call this our Health Inventory Program. The employee is evaluated in our Health Screening Center; which during the year is moved to various locations around the plant. This program has evolved somewhat since its inception to the point where it now includes a history and the measurement of over 40 separate anthropomorphical and biochemical variables. It is an extraction of data from this program that I wish to discuss today.

A synopsis of the parameters that are evaluated by our current program is covered by Table 1 which is in the record.

The medical history includes among other things information on hospitalizations, numbness in the hands, respiratory difficulties, liver problems, alcohol ingestion, anemia and current medications. We do a detailed smoking history. We inquire into the number of stillborns, miscarriages, birth defects.

Our evaluation includes chest x-ray, electrocardiogram, pulmonary functions, hematology, urinalysis, and a variety of blood chemistries, including lactic dehydrogenase (LDH), serum glutamic oxalacetic transaminase (SGOT), total bilirubin, alkaline phosphatase, BUN, uric acid, creatinine, calcium, total protein, albumin, and cholesterol.

The results are compiled and reviewed by a physician. Based upon the physician's evaluation, followup studies are instituted.

We recommend that each employee requests that we forward the results of his periodic health inventory evaluation on to his personal physician. We stress responsible followup; continuity of medical care.

In this study, the population of interest was defined to be production employees at one manufacturing location who worked for at least one year between 1942 and January 1972 in areas with potential vinyl chloride exposure. It was further defined to include only those individuals who were employees of the Midland Division between February 1967 and March 1974, the inclusive period of the health inventory program.

Based upon a review of industrial hygiene data, each individual was assigned to one of four exposure groups: high, intermediate, low and undefined. The categories were based on estimated time weighted average concentrations for an eight hour day (TWA). The high level was defined as exposures above 200 ppm for at least one month's duration; the intermediate level was 25 to 200 ppm; and the low level as less than 25 ppm. For 81 individuals insufficient industrial hygiene data was available to accurately estimate their exposures and they were placed in the undefined group. A subjective evaluation by industrial hygienists indicated that the exposures in this undefined group were, for the most part, in the low to intermediate range.

In placement of individuals in particular exposure groups, precedence was given first to a history of high, then intermediate, next undefined and finally low exposure.

Table 2 also in the record gives a breakdown as to the number of employees in each group and the number who voluntarily participated in the Health Inventory Program. The participation rate among the various exposure groups was about 80 percent.

As of March 1974, we were in the final stages of our fourth cycle through the plant. Because of major revisions in the Health Inventory Program in 1970, data before and after this date have been analyzed separately. This conveniently breaks our analysis down into a study of the first two cycles and the last two.

In the first two cycles, February 1967 to December 1970, 10 clinical parameters were evaluated. Two of them, serum protein and hemoglobin, had insufficient data and were discarded. Data of the remaining eight were analyzed: FVC (Forced Vital Capacity), FEV_1 (Forced Expiratory Volume - One Second), systolic blood pressure, diastolic blood pressure white blood count, total bilirubin, SGPT (Serum Glutamic Pyruvic Transaminase) and alkaline phosphatase. The mean value of each of these tests was determined for the exposure group and for a control group of matched pairs. The control group was matched for sex, age, smoking history, month of exam, and where possible master number. Our master numbers are sequential based upon date of hire. Master numbers of similar magnitude indicate similar lengths of employment. The only statistically significant deviation ($P < .05$) was for a decreased diastolic blood pressure on the high exposure group. All other tests in all exposure groups, including undefined exposure, showed no statistically significant differences. What's the clinical significance of this finding? I don't know.

A number of questions from the history have also been analyzed: shortness of breath; chronic cough; yellow jaundice, stomach, liver, intestinal trouble; numbness in hands and feet; cancer or malignant growth; anemia or blood problems. No significant differences were noted between the exposure and the matched pair control groups.

Similar analyses were made on selected laboratory data and questions of the last two health inventories, January 1971 to March 1974. Tables 3 and 4 give a list of parameters that were considered for this report.

The questions were similar to those asked previously. The laboratory studies included pulmonary functions, hemoglobin, white blood count, total bilirubin, SGOT (Serum Glutamic Oxalacetic Transaminase), LDH (lactic dehydrogenase), total protein, protein albumin, and protein globulin. During this period three separate techniques for alkaline phosphatase, involving three separate normal ranges, were utilized by our consulting laboratory. For this reason statistical analysis of the results of this study was not done. Review of the individual results revealed nothing of clinical concern. In all other parameters studied nothing of statistical significance was found.

We have studied various parameters of our employees health for over twenty years, including a number of those suggested by the proposed standard. We plan to continue this medical surveillance and plan to continue incorporating new techniques as they are developed and as they apply to our operation: automated multiphasic testing, computerized medical records, enzymatic studies, analysis of metabolic end products, chromosome studies, exfoliative cytology.

This report is a summary of our findings of past studies. Above 200 ppm some deviations were noted in various health parameters; below 200 ppm nothing of statistical significance has been observed.

A group from the Institute of Environmental and Industrial Health, University of Michigan, has done an extensive study of over 5000 employees of 32 plants involved in various phases of vinyl chloride

and polyvinyl chloride manufacturing. Their findings can be found in a series of articles entitled, "Occupational Acroosteolysis" in the Archives of Environmental Health (22, 61, January 1971). Our Midland location was one of the plants studied. They found no acroosteolysis in our work force.

As has been mentioned in previous testimony, a group of health researchers from Mt. Sinai New York Medical Center has also recently studied a group of our Midland location employees.

In Dr. Selikoff's preliminary evaluation he brings up some interesting clinical observations. Dr. Selikoff stated yesterday his evaluation is incomplete and further analyses of his data is needed. As Dow has indicated to Dr. Selikoff several times, we look forward to working with him in developing meaningful dose response information - of combining our twenty plus years of industrial hygiene data, our twenty plus years of medical surveillance data - with his expertise in occupational medicine. Our ultimate concern is the health of our employees.

TABLE 1.

HEALTH INVENTORY

Identification	Pulmonary Functions	Chemistries:
Work History	Vision	BUN
Family History	Hearing	Glucose
Smoking History	Intraocular Tensions	Uric Acid
Family Physician	Height	Creatinine
Medical History	Weight	Calcium
Medications	Blood Pressure	Bilirubin
X-Ray	Hematology	Protein Total
Electrocardiogram	Urinalysis	Albumin
		SGOT
		Alkaline Phosphatase
		LDH
		Cholesterol

TABLE 2.

EMPLOYEE PARTICIPATION IN HEALTH INVENTORY PROGRAM
BY EXPOSURE GROUP

	Total	High	Intermediate	Low	Undefined
Employees Of 1/68	335	118	63	73	81
Employees Of 1/74	276	102	54	63	57
Employees With One Or More Exams 2/67 To 3/74	277	93	56	64	64
Employees With One Or More Exams 2/67 To 12/70	239	83	44	54	58
Employees With One Or More Exams 1/71 To 3/74	219	72	44	56	47

TABLE 3.

PARAMETERS STUDIED
JANUARY 1971 TO MARCH 1974

SGOT (Serum Glutamic Oxalacetic Transaminase)
ALKALINE PHOSPHATASE
LDH (Lactic Dehydrogenase)
TOTAL PROTEIN
ALBUMIN
GLOBULIN
TOTAL BILIRUBIN
DIASTOLIC BLOOD PRESSURE
SYSTOLIC BLOOD PRESSURE
FVC (Forced Vital Capacity)
FEV (Forced Expiratory Volume - One Second)
HEMOGLOBIN

TABLE 4.

HEALTH INVENTORY QUESTIONS
CYCLES THREE AND FOUR

- SHORTNESS OF BREATH
- COUGH LASTING OVER THREE MONTHS
- NUMBNESS IN HANDS OR FEET
- YELLOW JAUNDICE
- LIVER TROUBLE
- ANEMIA OR BLOOD PROBLEMS
- CANCER OR MALIGNANT GROWTH

NEXT, I SHOULD LIKE TO CALL ON DR. BEN HOLDER, MEDICAL DIRECTOR OF THE MIDLAND DIVISION, WHO WILL DISCUSS THE RESULTS OF A STUDY OF THE MORTALITY EXPERIENCE OF WORKERS EXPOSED TO VINYL CHLORIDE DATING BACK TO 1942.

DR. HOLDER

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MORTALITY STUDIES

B. B. HOLDER
THE DOW CHEMICAL COMPANY
MIDLAND, MICHIGAN

MORTALITY STUDIES

My name is Ben Holder. I am an occupational physician. I am presently the Medical Director for the Midland Division of Dow Chemical U.S.A. I received a B.A. from Oberlin College in 1948 and M.D. from Wayne State University College of Medicine in 1952. I have been in the practice of occupational medicine for 20 years.

Today I would like to report on the long-term mortality experience of 594 chemical workers exposed to vinyl chloride in a controlled industrial environment between the years of 1942 - 1960. S-1

In this report we recognize that our total population size is small and does not readily lend itself to statistical analysis.

Data on those workers exposed to vinyl chloride levels above 200 ppm TWA suggest an apparent increase in overall malignancy rate. A decrease rate of malignancy was found where exposures were controlled below the level of 200 ppm TWA. No angiosarcomas of the liver were found at any level. S-2

The details of their exposures were previously reviewed in an environmental report of our polymer production facilities.

The population of interest was defined to be production employees in one manufacturing location who worked in areas with potential vinyl chloride exposure between 1942 and 1960. These employees were identified from annual departmental census lists. Through the annual census taken in January of each year, nearly all the men who worked for at least one year and about half the men who worked less than a year would be identified. The lists were reviewed over the specified years for five polymer production units. Exposure measurements were available for the two larger units, but not for the three smaller units. The determination of exposure categories was made independent of the medical data.

To investigate dose response relationships with respect to vinyl chloride, industrial hygiene data was reviewed for each job classification and the job was assigned an exposure level rating of low, intermediate, or high. The three categories were defined primarily based on estimated time-weighted average concentrations for an eight-hour day (TWA). The low level was defined as TWA concentrations below 25 ppm vinyl chloride; the intermediate level was defined as 25 to 200 ppm, and the high level was defined as 200 to 300+ ppm. S-3

The high exposure level was also assigned to several jobs with time-weighted average concentrations in the intermediate range, but where frequent unpredictable excursions above 1000 ppm were known to occur. Changes in exposure level category for a given job because of improved industrial hygiene practices were properly recognized. Since insufficient data were available to determine TWA estimates for the three smaller units, a fourth category of indeterminate exposure was defined for individuals working in these areas. A subjective evaluation of the three units by industrial hygienists indicated that exposures were, for the most part, in the low to intermediate range, with occasional excursions to high levels.

Because of job mobility, many employees experienced exposure at more than one concentration level. Individuals in the study population were assigned to exposure groupings based on the highest exposure experienced for one or more months. This procedure insured that the lowest exposure group contained individuals experiencing only low exposure while the higher exposure groups would have included individuals

with mixed high and low exposures. In the analysis, duration of exposure was separated into two categories: less than one year and one year or longer. The dichotomy was chosen because of the small number of individuals involved in the study. For the intermediate and high exposure groups, length of exposure at lower levels was not considered in assigning the individual to less-than-one-year or one-plus-years categories. Thus, an individual exposed at high levels for six months, and at lower levels for ten years, would be classified in the high category with less than one year of exposure at that level. This strategy preserved the identity of the highest concentration level rather than that of the accumulative dosage.

Previous studies at this company location have indicated that individuals who worked in an arsenicals production area prior to 1956 were liable to an excess cancer risk. A paper dealing with the mortality experience of the arsenicals production employees has been submitted for publication. There were 72 individuals in the present study who were exposed to both arsenicals and vinyl chloride. The mortality experience of the vinyl chloride cohort is summarized with the arsenicals employees included and excluded. The arsenicals employees have been excluded from the tables that deal with dose response relationships with respect to vinyl chloride.

The numbers of expected deaths were determined by summing the person years lived by employees over five calendar periods, by ten year age groups. The numbers obtained were then multiplied by the appropriate U.S. white male mortality rates and accumulated. U.S. data for the years 1942, 1947, 1952, 1957, 1962, and 1967 were utilized along with projected rates for 1971.

Followup of employees who left the company was obtained through interviews, review of county and state records and through the social security administration.

Copies of the death certificates have not been obtained for two deaths among former company employees. Each of these decedents had been exposed to vinyl chloride for less than one year. The two deaths have been included in the all causes category throughout the paper, but have not been apportioned to particular cause of death categories.

The vital and employment status of the total cohort of 594 employees is presented in slide 4 by level of highest exposure. Seventeen of the 148 individuals who left the company were not successfully traced. Sixteen were not traced because the original cohort population was expanded after the social security check was performed. One other individual was known to have left the country. Of the 121 individuals successfully traced, 11 decedents and 59 persons still alive were identified through interviews and county death records. The remaining 61 former employees were traced through the social security administration. Eleven of the 61 individuals were identified as deceased and the remaining 50 subjects were assumed to be living. S-4

Slides 5, 6, and 7 summarize the mortality experience, by cause, of the total cohort population and of the population less those employees exposed to arsenic. Seven of 10 deaths among the 72 individuals who worked with arsenicals were due to neoplasm. Only 1.9 deaths due to neoplasm were expected for particular sub-group of employees. Case summaries for seven deaths are shown in slide 8. S-5 S-6 S-7 S-8

Observed deaths among workers not exposed to arsenicals were 91 percent of the expected deaths based on the U.S. white male population. The background mortality experience for chemical production workers at this manufacturing location is 15 to 20 percent below the U.S. white male population. However, less extensive followup has been undertaken of former employees, especially those who left the company during the 1940's.

The three deaths due to cirrhosis of the liver occurred among individuals who left the company prior to 1950 and who were exposed to vinyl chloride for less than one year. One of these individuals was discharged in 1948 because of alcoholic intoxication. No deaths due to angiosarcoma or other liver malignancies were observed. Nor have these diagnoses appeared on the death certificates as secondary causes of death.

Again, as previously stated total malignancies were less than expected, 13 versus 15.4, among employees exposed to vinyl chloride, but not arsenicals.

The mortality experience of the cohort, exclusive of the arsenicals workers, was examined with respect to exposure grouping. Slide 9 shows length of employment in areas involving vinyl chloride exposure in relation to level of exposure for each of the four exposure groupings. Total length of exposure was less among the individuals in the low exposure group than among the other exposure groups. One hundred twenty-seven employees in the low exposure group worked for under one year in the production areas of interest. A probable explanation for this occurrence is that more entrance jobs were found in the dry-end of the polymerization processes where exposures to vinyl chloride were low. Many of the employees, who remained with the

S-9

units and established seniority, eventually worked in the higher exposure areas. The distribution of the malignant neoplasms with respect to exposure levels was suggestive of a possible dose response relationship. As seen from slide 10, S-10
although the numbers of deaths were small and therefore were not tested for statistical significance, nine of the thirteen malignancies were observed in the high exposure group. Slide 11 shows the arsenical workers included. To allow S-11
for latent effects, the mortality experience 15+ years after initial exposure was examined in slide 12. Eight S-12
of nine malignancies in the high exposure group occurred among individuals 15+ years after initial exposure. On the other hand, only four malignancy deaths were observed among the remaining exposure groups with just one of these deaths occurring 15+ years after first exposure. The expected numbers of deaths due to neoplasms in the remaining exposure groups were 10.3 for total years and 5.6 for 15+ years after initial exposure.

Case summaries for the 13 deaths due to malignant neoplasms are shown in slide 13. Seven of the nine individuals S-13
in the high exposure group had worked for more than ten years in exposure areas. The remaining two individuals worked for five and nine years, respectively. There were two deaths for which neoplasms were recorded on the death certificate as secondary rather than underlying causes of death. In each case the death was coded to the category diseases of the cardiovascular system. Slide 14 summarizes S-14
the exposure history for these two decedents. Both worked for short periods of time in low exposure areas.

While one must consider vinyl chloride to be a carcinogen, we feel it is appropriate to mention several observations that would give support to an immuno-suppressant or co-carcinogenic effect of the material. Fully recognizing that this is limited data, we present this posture only to encourage further research. These data are in reference to slide 13.

1. Leukemia (acute granulocytic) -- During the last 10 years of employment he was not exposed to any vinyl chloride but worked in an area associated with benzene.

2. Adeno carcinoma of the rectum -- Mother, 2 brothers and one sister died of a malignancy.

3. Of the total of four lung malignancies in the high exposure group, three and probably the fourth had a history of cigarette smoking. Again, this raises the question as to the advisability of smoking, particularly when working with environmental carcinogens.

4. Additional support to this and again in recognition of a very small population, there were seven malignancies in the group exposed to arsenic and vinyl chloride as opposed to 1.9 expected. The SMR (Standard Mortality Ratio) for malignancies in the vinyl chloride population excluding arsenic would be 0.8. The SMR, however, for a population with vinyl chloride plus arsenic exposure was found to be 3.6.

Overall mortality experience of the population was better than the expected for the U.S. male population. No angiosarcomas or liver tumors were found. S-15

No adverse effect from malignancy was apparent in that population where exposures to vinyl chloride were controlled below 200 ppm TWA. In workers exposed above 200 ppm a non-statistical increase in overall experience was noted.

June 21, 1974

Long Term Mortality Experience Of 594 Chemical Workers Exposed To Vinyl Chloride In A Controlled Industrial Environment Between The Years 1942 - 1960.

Slide 1

1. Overall Mortality Experience Of The Population Was Better Than U.S. Male
2. Apparent Malignancy Rate
   DECREASED BELOW 200 ppm
   INCREASED ABOVE 200 ppm
3. No Angiosarcoma's
4. No Liver Tumors

Slide 2

EXPOSURE LEVELS - TWA

HIGH – 200-300+ ppm

INTERMEDIATE – 25-200 ppm

LOW – <25 ppm

INDETERMINATE

Slide 3

Vital And Employment Status Of Study Group As Of January 1, 1974, By Exposure Category

	Low TWA <25 ppm	Intermediate TWA 25 200 ppm	High TWA 200-300+ ppm	Unmeasured
Total Population	*197*	*78*	*192*	*127*
Still Working	95	44	119	51
Retired	16	12	21	22
Deceased (company record)	20	9	22	15
Left Company	66	13	30	39
Alive	58	10	22	19
Deceased	7	3	8	4
Unknown	1	–	–	16
Total Population Less Arsenic Exposed	*181*	*73*	*163*	*105*
Still Working	89	42	100	33
Retired	15	12	16	21
Deceased (company record)	16	8	20	13
Left Company	61	11	27	33
Alive	54	8	20	16
Deceased	7	3	7	4
Unknown	–	–	–	13

Slide 4

Observed And Expected Deaths, By Cause, Including And Excluding Those Employees Exposed To Arsenic, 1941-1973

	Total Population		Total Population Less Arsenic Exposed	
	Obs.	Exp.	Obs.	Exp.
All Causes	88	96.2	78	85.7
Total Malignancies	20	17.3	13	15.4

Slide 5

TOTAL MALIGNANCIES

	Total Population		Total Population Less Arsenic Exposed	
	Obs.	Exp.	Obs.	Exp.
Cancer Of The Respiratory System	7	5.6	4	5.0
Cancer Of The Digestive System And Peritoneum	7	5.1	5	4.5
Malignant Neoplasm Of Stomach	1	NC*	1	NC
Malignant Neoplasm Of Liver And Intrahepatic Bile Ducts	0	NC	0	NC
Malignant Neoplasm Of Intestines Or Rectum	5	NC	3	NC
All Other Digestive And Peritoneum Ca.	1	NC	1	NC
All Other Sites	6	6.6	4	5.9

*Not Compiled

Slide 6

OTHER DISEASES

	Total Population		Total Population Less Arsenic Exposed	
	Obs.	Exp.	Obs.	Exp.
Diseases Of The Cardio-vascular System	41	47.5	40	42.6
External Injuries	11	12.7	10	11.1
Cirrhosis Of Liver	3	2.9	3	2.6
All Others	11	15.8	10	14.0
(Death Certificates Not Available)	4	--	4	--

Slide 7

Case Summaries Of Seven Subjects Who Were Exposed To Arsenic As Well As Vinyl Chloride And Whose Death Was Due To Cancer

Date of First Vinyl Chloride Chlorinated Monomers Exposure and Duration, mo.		Year of Death	Age at Death	Primary Site of Cancer Tumor	Autopsy	Family Cancer History	Smoking History
High Exposure							
1941	220 (272 total)	1973	63	Lung	No	Brother	Unknown
1942	4	1971	66	Colon	--	Unknown	Unknown
Low Exposure							
1949	3	1959	60	Lung	No	No	¾ pk/day
1949	111	1964	68	Lung	Yes	No	1 pk/day
1952	3	1971	41	Brain	No	No	1¼ pk/day
Undetermined Exp.							
1951	177	1966	49	Colon	--	Unknown	Unknown
1947	86	1959	60	Prostate	--	Unknown	Pipe

Slide 8

Duration Of Exposure By Level Of Exposure For Each Exposure Grouping (Arsenic Workers Excluded)

Exposure Group And Level Of Exposure	No. Of Employees With Cumulative Exposure Of			
	< 1 Year	1-9 Years	10-19 Years	20+ Years
High Exposure Group				
Low to high levels	33	64	39	27
High levels only	73	71	19	0
Intermediate Exposure Group				
Low to intermediate levels	29	33	6	0
Intermediate levels only	32	36	5	0
Low Exposure Group				
Low levels only	127	50	3	1
Unmeasured Exposure Group				
Unmeasured or low levels	39	44	16	6

Slide 9

Observed And Expected Deaths By Exposure Intensity And Duration Of Exposure, 1941-1973 (Arsenic Workers Excluded)

Exposure Intensity and Duration		Deaths Due To All Causes		Deaths Due To Malignant Neoplasms	
		Observed	Expected	Observed	Expected
High Exposure	Total	27	28.2	9	5.1
	Less than 1 year	14	12.8	3	2.2
	1+ years	13	15.4	6	2.9
Intermediate Exposure	Total	11*	16.5	2	2.9
	Less than 1 year	5	7.9	0	1.4
	1+ years	6	8.6	2	1.5
Low Exposure	Total	23*	23.4	1	4.1
	Less than 1 year	16	13.7	0	2.4
	1+ years	7	9.7	1	1.7
Unmeasured Exposure	Total	17	17.6	1	3.3
	Less than 1 year	5	5.3	1	1.0
	1+ years	12	12.3	0	2.3

*Cause of death was not available for four decedents, *three* in the low exposure group and *one* in the intermediate exposure group, all with less than one year of exposure

Slide 10

Observed And Expected Deaths By Exposure Intensity And Duration Of Exposure, 1941-1973 (Arsenic Workers Included)

Exposure Intensity and Duration		Deaths Due To All Causes		Deaths Due To Malignant Neoplasms	
		Observed	Expected	Observed	Expected
High Exposure	Total	30	33.0	11	6.0
	Less than 1 year	15	14.3	4	2.5
	1+ years	15	18.7	7	3.5
Intermediate Exposure	Total	11*	17.2	2	3.0
	Less than 1 year	5	7.9	0	1.4
	1+ years	6	9.3	2	1.6
Low Exposure	Total	27	25.6	4	4.5
	Less than 1 year	19	15.5	2	2.7
	1+ years	8	10.1	2	1.8
Unmeasured Exposure	Total	20	20.4	3	3.8
	Less than 1 year	5	6.4	1	1.2
	1+ years	15	14.0	2	2.6

*Cause of death was not available for four decedents, *three* in the low exposure group and *one* in the intermediate exposure group, all with less than one year of exposure

Slide 11

Observed And Expected Deaths 15 Years After Initial Exposure By Exposure Intensity And Duration Of Exposure (Arsenic Workers Excluded)

Exposure Intensity and Duration		Deaths Due To All Causes		Deaths Due To Malignant Neoplasms	
		Observed	Expected	Observed	Expected
High Exposure	Total	20	16.4	8	3.2
	Less than 1 year	9	8.6	3	1.3
	1+ years	11	9.8	5	1.9
Intermediate Exposure	Total	4	7.8	0	1.4
	Less than 1 year	2	3.7	0	0.7
	1+ years	2	4.1	0	0.7
Low Exposure	Total	9*	12.1	1	2.4
	Less than 1 year	7	6.6	0	1.3
	1+ years	2	5.5	1	1.1
Unmeasured Exposure	Total	10	9.0	0	1.8
	Less than 1 year	2	2.6	0	0.5
	1+ years	8	6.4	0	1.3

*Cause of death was not available for two decedents in low exposure group with less than 1 year of exposure

Slide 12

Case Summaries Of 13 Subjects Who Were Not Exposed To Arsenic And Who Died From Cancer

Date of First Vinyl Chloride Exposure and Duration, mo.		Year of Death	Age at Death	Primary Site of Tumor	Autopsy	Family Cancer History	Smoking History, Pk/Day
	High Exposure						
1950	19 (108 total)	1964	54	Stomach	Yes	Mother	Unknown
1949	41 (209 total)	1966	53	Lung	Yes	Mother	1 - 30 yr
1951	4 (120 total)	1968	69	Lung	Yes	No	Unknown
1943	203 (287 total)	1969	56	Rectum	No	Mo,Bro(2),Sis(1)	Unknown
1941	222 (317 total)	1969	61	Squamous cell site (?)	Yes	No	1 - 20 yr
1950	65 (119 total)	1971	45	Leukemia	No	No	No
1945	54 (330 total)	1972	54	Lung (?)	No	No	2 - 36 yr
1950	5 (191 total)	1972	62	Lung	No	No	½ - 30 yr
1948	8 (64 total)	1973	62	Colon	No	No	1 - 45 yr
	Intermediate Exposure						
1954	25 (51 total)	1958	61	Brain	?	No	Unknown
1945	30 (84 total)	1960	71	Pancreas	No	Unknown	Unknown
	Low Exposure						
1952	66	1970	51	Lung	Yes	Unknown	Unknown
	Undetermined Exposure						
1952	5 (14 low exposure)	1954	60	Cecum	Yes	Father	Unknown

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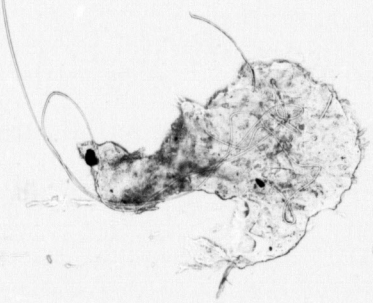
Slide 13

Case Summaries [illegible] Deaths For Which Malignant Neoplasms Were Secondary To The Underlying Cause Of Death

	Subject 21	Subject 22
Cause of death from death certificate	Acute pulmonary edema (immediate) myocardial infarction (hours) other significant conditions - bronchiogenic carcinoma right lung	Massive old myocardial infarction (7 days) sigmoid carcinoma with A-R resection (8 months)
Date of first vinyl chloride exposure and exposure duration	1950 3 months low exposure	1950 1 month low exposure
Year of death	1968	1972
Age at death	50	50
Autopsy	Yes	Yes
Family cancer history	No	No
Smoking history	1 package/day	1 package/day
Other significant exposure	None	None

Slide 14

1. Overall Mortality Experience Of The Population Was Better Than U.S. Male
2. Apparent Malignancy Rate
   DECREASED BELOW 200 ppm
   INCREASED ABOVE 200 ppm
3. No Angiosarcoma's
4. No Liver Tumors



Slide 15

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